B BRAUN
SHARING EXPERTISE

PRESCRIPTION | PATIENT ACCESS | PREPARATION / COMPOUNDING | APPLICATION | DISCHARGE MANAGEMENT

CLINICAL NUTRITION IN ONCOLOGY

NUTRIENTS ARE KEY FOR LIFE

B. BRAUN – YOUR RELIABLE PARTNER IN NUTRITION THERAPY

Those who are striving to improve people's health must examine the tasks at hand and meet them head on. They must constantly work to expand their understanding, recognize new opportunities and be passionate and committed to finding effective solutions. This philosophy unites us at B. Braun with the larger healthcare community, and we express it with our promise of sharing expertise.

As a leading company in the area of Nutrition Therapy, we constantly seek constructive dialog with patients, doctors, and healthcare professionals in order to gain insights for progress for treatments and routines in this field. Our guiding aims: Reducing risks. Simplifying procedures. Enhancing safety.

Based on this exchange, our broad knowledge and more than 175 years of experience, B. Braun is focused on the most important and challenging aspects of Nutrition Therapy. We aim to develop helpful products and to define how to use and combine them in the most efficient way. Join with us – as your reliable partner – in setting higher standards for the safety of patients and healthcare professionals.

NUTRITION THERAPY IN CANCER FOR A BETTER QUALITY OF LIFE

Cancer is one of the major healthcare burdens worldwide and one of the leading cause of death in many countries. Progress in anti-cancer therapies has improved cancer survival rates. [1,2]

Malnutrition is a common problem in cancer patients that has been recognized as an important component of adverse outcomes, including increased morbidity and mortality and decreased quality of life. [3,4]

Cancer patients commonly suffer from weight loss, which serves as an indicator of poor prognosis in cancer patients. Cancer cachexia is observed in approximately 50% of patients with cancer. [5,6]

Nutrition plays an important role in many aspects of cancer development and is an important supportive therapy throughout the whole pathway of cancer treatment. Adequate nutrition support can help cancer patients maintain weight and lean body composition, offering better recovery from nutrition impact symptoms and improving quality of life. [3,7,8,9]

CLINICAL NUTRITION IN ONCOLOGY
IMPROVING NUTRITION FOR BETTER RECOVERY

How Nutrition Therapy improves cancer care

Nutritional intervention can improve clinical outcomes in certain cancer types (e. g. head and neck cancer) or treatments (e. g. chemo-radiotherapy) where reduced food intake is prevalent and is not accompanied by severe metabolic derangements. In such patients, conventional screening, assessment and appropriate nutritional intervention is predicted to have beneficial effects. [11]

Malnutrition and cachexia in cancer

Malnutrition is a major cause of morbidity and mortality in tumor patients [13] and causes negative effects on tissue, body structure, organ functions as well as on the overall clinical course. [14] Up to 80% of all tumor patients have already lost weight when diagnosed. [13] This initial weight loss is particularly pronounced in patients with pancreatic, gastric, esophageal and head and neck tumors. 30% of these patients experienced already a significant weight loss of 10% or more of their body weight at the time of diagnosis. [13] Cachexia is one specific metabolic form of malnutrition that occurs particularly at advanced cancer stages. [15] Criteria for tumor cachexia are the combination of malnutrition and systemic inflammatory reaction. A nutritional deficiency of this sort has an unfavorable effect on the quality of life and the prognosis of the tumor patient. Both the response to antitumor therapies and the survival time are negatively affected. [16] Furthermore, there is also often a clear economic burden resulting from nutritional deficiency due to the frequent and longer hospital stays and higher therapy costs associated with it.

Cancer types related to malnutrition

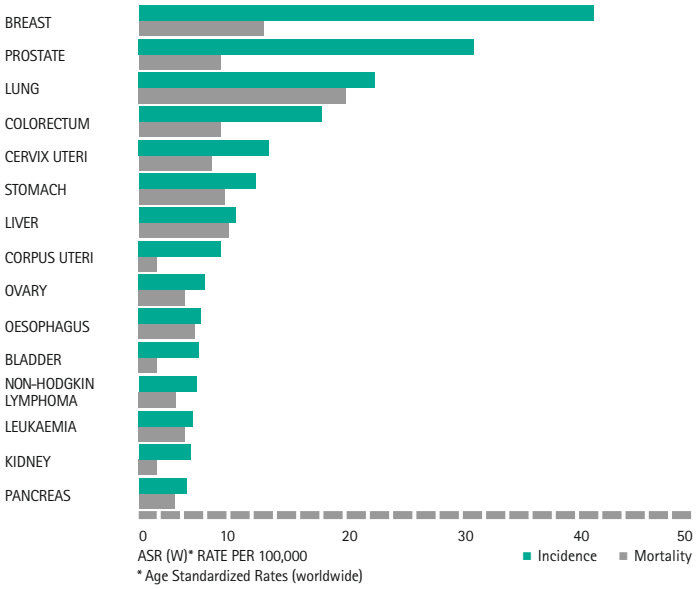
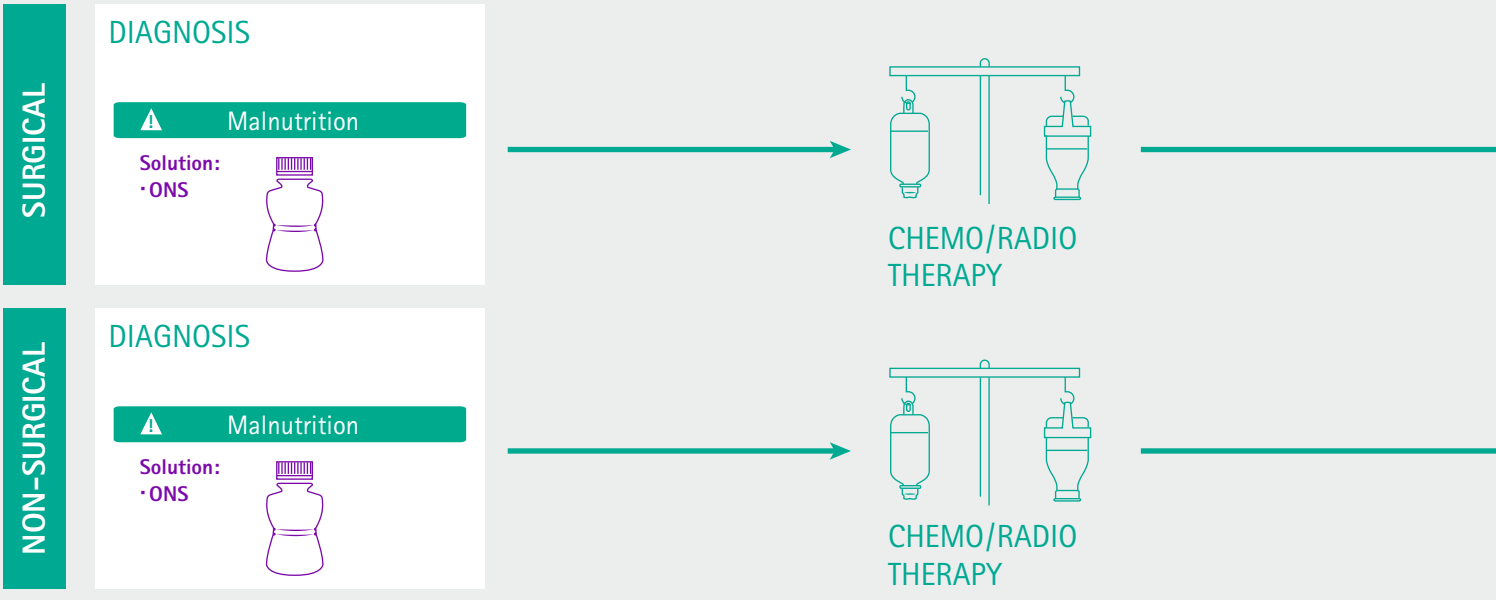


FIGURE 1 | Estimated age-standardised incidence and mortality rates: both sexes. [12]

NUTRITIONAL SUPPORT CARE FOR CANCER PATIENTS

B. Braun can support you and your patients during cancer therapy with several nutrition solutions to counteract malnutrition.



ONS: Oral Nutrition Supplement; **PN:** Parenteral Nutrition; **EN:** Enteral Nutrition; **HEN:** Home Enteral Nutrition; **HPN:** Home Parenteral Nutrition

IMPORTANCE AND BENEFITS OF NUTRITION SUPPORT IN CANCER

Goals of Nutrition Therapy in cancer treatment (ESPEN Guideline Cancer 2016)

- Maintain or improve food intake
- Mitigate metabolic derangements
- Maintain skeletal muscle mass and physical performance
- Reduce the risk of reductions or interruptions of scheduled anti-cancer treatments
- Improve quality of life

Nutrition Therapy in malnourished at risk of malnutrition cancer patients

- May help to improve body weight and energy intake [11]
- Can reduce the incidence of postoperative infectous and non-infectous complications, together with a positive effect on length of hospitalization [4]
- May improve physical activity and quality of life [11]
- Can diminish negative effects of radiotherapy on nutrition status [11]
- May improve survival [11,16]
- Can improve quality of life [7,11]
- May reduce cancer treatment toxicity [10,11]

NUTRITION THERAPY CAN IMPROVE QUALITY OF LIFE [7]

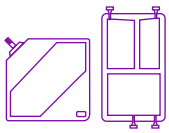
NUTRITION THERAPY MAY REDUCE RISK OF INFECTIONS [4]

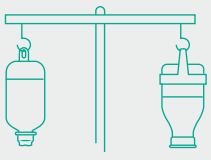
NUTRITION MAY REDUCE SIDE EFFECTS OF CANCER TREATMENT [10,11]

SURGERY*

⚠ Malnutrition

Solution:
- PN
- EN or
- PN & EN



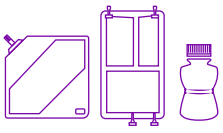


CHEMO/RADIO THERAPY

TREATMENT CONTINUATION (HOME SETTING)

⚠ Malnutrition

Solution:
- HEN
- HPN or
- ONS



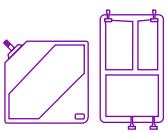
TREATMENT CONTINUATION (HOME SETTING)

⚠ Malnutrition

Solution:
- HEN and/or
- ONS

⚠ Severe Malnutrition

Solution:
- HEN or
- HPN



* In cancer patients undergoing surgery, is recommended to use a formula with immunaenutrients, including EPA and DHA [11]

NUTRITION IN ONCOLOGY
ENHANCED SAFETY DURING ALL STEPS

PRESCRIPTION

Prior to prescribing Clinical Nutrition in connection with oncological treatment, the nutritional regimens and the optimal pathway of delivery are decided based on individual patient characteristics so as to ensure adequate nutritional support.

B. Braun offers a wide range of parenteral and enteral solutions and services to cover the specific needs of oncology patients.

PATIENT ACCESS

After phycisians have chosen a specific nutritional strategy, they will prepare the patient for the appropriate access route.

B. Braun medical devices make it easy for the healthcare team to administer Enteral and Parenteral Nutrition products in a safe and efficient manner.

We have identified various steps which represent standard processes in providing Nutrition Therapy. For critically ill patients, B. Braun offers a wide range of products for each of these process steps.

These products are designed to provide advanced care while meeting the needs of healthcare professionals with regards to efficiency and risk reduction.

PREPARATION / COMPOUNDING

In this step, the prescribed products are prepared for subsequent parenteral and / or enteral application. To support compatibility for the parenteral solution, B. Braun provides easy to mix multi-chamber bags, supplements, and compatibility tools. The enteral diets are delivered as ready-to-use solutions.

APPLICATION

The defined nutrition route is decisive for the application of Clinical Nutrition. Infusion pumps with dedicated sets for Enteral and / or Parenteral Nutrition solutions to support correct administration. For patients with stress-induced hyperglycemia, glucose management systems help control blood glucose levels in order to prevent hyper- and hypoglycemia as well as blood glucose variability. Tube misconnections are a major concern, especially in an Oncology setting. By offering dedicated enteral and parenteral administration sets, B. Braun provides a clear equipment-based means of enhancing patient safety.

DISCHARGE MANAGEMENT

After leaving the hospital, patients often continue Nutrition Therapy at home.

B. Braun provides convenient solutions to increase patients' mobility even when treatment is required after the hospital stay.

Clinus® Software

EN PN

Supports physicians and pharmacists to manage the Clinical Nutrition workflow from admission to discharge of the patient.

NuTRIflex® Omega

EN PN

(For mandatory drug information please refer to page 40)

The lipid component (Lipoplus®/Lipidem®) in NuTRIflex® Omega is rich in Eicosapentaenoic acid (EPA) and Docosahexaenoic acid (DHA), derived from fish oil.

MALNUTRITION IN CANCER NUTRIENTS ARE THE KEY

Malnutrition and cachexia are frequent in Oncology patients and are indicators of poor prognosis. Enteral Nutrition should be started if undernutrition already exists or if food intake has been markedly reduced for more than 7 days. Enteral formulas with an appropriate concentration of protein and calories may be considered. When the enteral route cannot be used, Parenteral Nutrition both at the hospital setting or at home should be considered. [4,11,17,18]

Cachexia, inflamation and Omega-3 fatty acids

In cachectic patients, metabolic modulators such as progestins, steroids and possibly Omega-3 fatty acids, may help to improve the nutritional status. [11,15] Enteral or Parenteral Nutrition is indicated preoperatively in cancer patients undergoing surgery. [17] During radiotherapy of head/neck and gastrointestinal region, dietary counseling and ONS may prevent weight loss and interruption of radiotherapy. [11,20,21] The NuTRIflex® Omega and Nutricomp® ranges contain EPA and DHA from fish oil sources.

EN suitable for Enteral Nutrition PN suitable for Parenteral Nutrition

Nutricomp® Energy HP/Energy HP Fiber EN PN

Nutricomp® Energy HP is a high caloric, high protein nutritionally complete formula, enriched with fish oil. According to the current ASPEN [19] and ESPEN [11] guidelines a sufficient energy and protein supply help to decrease complications and improves the nitrogen balance.

Nutricomp® Peptid EN PN

Nutricomp® Peptid is a normocaloric, nutritionally complete dietary food, with protein as defined oligopeptides.

Nutricomp® Drink HP EN PN
Nutricomp® Drink 2.0 kcal Fibre

Nutricomp® Drink HP and Nutricomp® Drink 2.0 Kcal are ONS with a high concentration of energy and high value protein enriched with fish oil.

Vasco® gloves, sterile and non-sterile

EN PN

The wide range of Vasco® gloves is available in sterile and non-sterile, latex and latex-free versions, to suit all needs and help protect users from contact with hazardous drugs. The sterile versions of Vasco® gloves are recommended for drug preparations in aseptic conditions.

Softasept® N

EN PN

(For mandatory drug information please refer to page 45)

Softasept® N is a fast drying ready-to-use alcoholic solution for skin disinfection, before injections and venous punctures (exposure time: 15 s). It is active against bacteria (incl. MRSA, TbB) and fungi; enveloped viruses (incl. HBV, HCV, HIV) and effective against rota- and poliovirus.

Askina Secure® IV

EN PN

Askina Secure® IV is a transparent dressing which allows an easy and stable fixation of the catheter and reduces the risk of catheter movement which could lead to extravasations.

SAFE ACCESSES FOR PARENTERAL AND ENTERAL

Based on the required Oncology treatment and the corresponding Nutrition Therapy, the appropriate access route will be defined.

Enteral Access

B. Braun is working together with the Global Enteral Device Supplier Association (GEDSA) to help introduce new international standards to reduce the risk of tubing misconnections with medical devices. The new Enteral Nutrition Feeding Tube range was designed with the ENFit® connector to meet these standards and enhance patient safety.

Parenteral Access

Based on the prescribed Parenteral Nutrition, the patient access (peripheral / central venous) is chosen. Most Parenteral Nutrition solutions are of high osmolarity and thus require a central venous line. However, special formulas for peripheral application are also offered.

EN suitable for Enteral Nutrition PN suitable for Parenteral Nutrition

Celsite® Safety EN PN

The new Celsite® Safety port is especially developed and adapted for the long term infusion of nutrition especially for cachexies patients. It features higher wearing comfort and due to the 10F silicon catheter a greater flow rate.

Certofix® protect Trio EN PN

Antimicrobially modified triple lumen catheter sets for catheterization of the vena cava according to the Seldinger method with the possibility of intra-atrial ECG lead. Certofix® protect reduces the risk of catheter related blood stream infections.

Nutritub® ENFit® EN PN

Nasal feeding tubes: Polyurethane feeding tubes for naso-gastric and naso-intestinal tube feeding with ENFit® connector specifically designed to prevent misconnections with IV lines.

EasyComp EN PN

EasyComp is a GAMP 5-validated compatibility program to allow the user to check if a Nutrition regimen will be physicochemically stable. The program supports the hospital pharmacists in their use of B. Braun TPN products.

NuTRIflex® Omega EN PN

(For mandatory drug information please refer to page 40)

NuTRIflex® Omega can be supplement with vitamines, trace elements and additional electrolytes. Compatibility data can be obtained from the manufacturer.

BENEFIT WITH REGARD TO PREPARATION & COMPOUNDING

Cancer treatments often cause symptoms which increase a patient's risk of suffering from malnutrition. Moreover, due to cancer-related metabolic changes (insulin resistance, increased protein breakdown), patients often require tailored Parenteral Nutrition.

Normally, tailored Parenteral Nutrition is prepared at the hospital pharmacy by compounding different components (amino acids, lipids, trace elements, etc.) into a single mixing bag or by supplementing 3-chamber bags with the necessary components. B. Braun offers tailor-made or standardized solutions for a lot of different needs.

EN suitable for Enteral Nutrition PN suitable for Parenteral Nutrition

Tracutil® and electrolyte concentrates EN PN

(For mandatory drug information please refer to page 44)

Product range of trace elements (Tracutil®) and electrolyte concentrates to supplement Parenteral Nutrition regimens according to the specific needs of the patients. Compatibility can be checked in advance with the EasyComp Software.

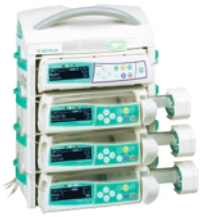
Single Nutrients EN PN

(For mandatory drug information please refer to page 41-44)

Product range of amino acids solutions (Aminoplasmal®), lipid emulsions (Lipoplus®, Lipofundin® MCT/LCT), and Glucose for the preparation of all-in-one regimens.

Nutrimix® compounding bags EN PN

EVA bags for short term storage, barrier bags for long-term storage, dual-chamber bags for lipids separation, as well as accessories.

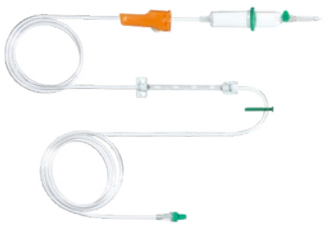


B. Braun Space Infusion Pumps EN PN

B. Braun Space pumps deliver Nutrition and drugs with highly accurate flow rates. The integrated customized Drug Library configuration includes Clinical Nutrition solutions used in the hospital which can also be individualized by freely programmable phases (Ramp and Taper Mode). Moreover, all therapy data are transfered from the pumps to the hospital information system for detailed and reliable documentation.

Enteroport® plus pump EN PN

Enteroport® plus is a small Enteral Nutrition pump, lightweight design, suitable for hospital and home care, quiet pump operation, turnable by 360 degrees, ergonomic shape for better grip and easy loading of pump cassette (delivery set).



Infusomat® Space Line SafeSet EN PN

The dedicated B. Braun SafeSet lines allow safe priming without fluid leakage due to the new protective cap lined with hydrophobic membrane. The infusion pump recognizes in time an empty running container due to the in-build air stop membrane. When removing the infusion line from the pump a set-based clamp prevents freeflow of hazardous drugs.

PRESCRIPTION PATIENT ACCESS PREPARATION

ACCURATE APPLICATION IN NUTRITION THERAPY

In the hospital setting, B. Braun's "One Infusion System for all Therapies" approach makes it possible to use one pump along the clinical pathway for hospital applications, setting the standard for clinical processes.

B. Braun understands the requirements for safe administration of clinical nutrition. Beds equipped with the B. Braun Space system do not need additional nutrition pumps, as these pumps are suitable for diverse therapies. This can not only save time with regards to user training, it can also cut costs for maintenance and service. The automated Space GlucoseControl System keeps the blood glucose level in a defined range in order to help avoid the risk of hypo- and hyperglycemia as well as blood glucose variability. For less complex needs, Enteroport® plus accurately delivers enteral formulas in an easy-to-handle, intuitive and user-friendly way.

EN suitable for Enteral Nutrition PN suitable for Parenteral Nutrition

Enteroport® plus Set EN PN

The ENFit® connector system is specifically designed for Enteral Nutrition administration by Enteroport® plus enteral pump.

Infusomat® Space Lines Type Enteral Nutrition EN PN

The ENFit® connector system is specifically designed for Enteral Nutrition administration by Space pump enteral.

Enteral Syringe ENFit™ EN PN

The B. Braun Perfusor Space pump in combination with the Enteral Syringe ENFit™ allows accurate delivery of enteral nutrition, important for pediatric ICU. Misconnections are prevented by the female ENFit™ connectors which are incompatible with IV connections.

Discharge Planning

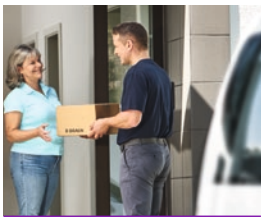
After notification from the hospital, the care manager will contact everyone involved in the care giving process and collect all necessary information.

Nursing Protocols

For the right and safe treatment at home, each step of the infusion is explained to healthcare professionals, the relatives and the patients in customized nursing protocols.

Procedure Kits

Based on the nursing protocols for infusion, B. Braun is offering nursing kits that contain all the necessary items for the connection and disconnection of infusion systems.



Delivery Service

The care manager organizes the delivery of the products needed. This implies contacting the pharmacy, a delivery service and a home care service to arrange the treatment.

Training for Caregivers

The care manager trains the nurses, the patient or relatives to provide the right conditions are in place for a safe home treatment.

PRESCRIPTION | PATIENT ACCESS | PREPARATION

BENEFIT WITH REGARD TO DISCHARGE MANAGEMENT

After hospitalization, patients may have to stay on IV medication, or continuing either their parenteral or enteral treatment at home or in alternative care settings. Discharge Management integrates all activities which are required to provide continuous support of the patient and hand over to nursing services.

B. Braun provides product and service systems for the treatment of patients after discharge from the hospital. A high standard of safety can be assured – especially in combination with the B. Braun safety portfolio.

EN suitable for Enteral Nutrition PN suitable for Parenteral Nutrition

Backpack

Parenteral Nutrition must be applied at a very moderate speed. If you are up and mobile you really do not want to be bound to your infusion stand and at home all day. You therefore have the possibility to take the bag of Parenteral Nutrition with you in a pouch or backpack.

Nutrition port Celsite® Safety

The new Celsite® Safety port is especially developed and adapted for the long term infusion of nutrition also in the ambulatory parenteral treatment of malnutrition.

Medical Devices and IV fluids

All products shown on the previous pages can also be used for infusion therapy at home.

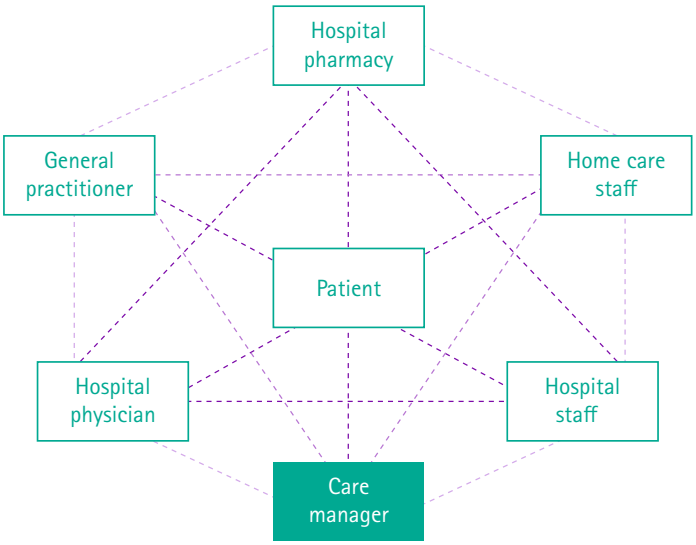
Dressings

Dressings are a cornerstone for the proper infusion before, during, and after the treatment. Our Askina® product line consists of a wide selection of dressings which are designed to fit to your individual needs.

TREATMENT CONTINUATION (HOME SETTING)
INDIVIDUAL NEEDS AND REQUESTS

OUR SERVICE AT HOME

We offer continuous high quality care to your home Parenteral and Enteral Nutrition patients. Over the last decade in Europe we have developed a treatment continuation (home setting) service for our patients. We believe that the tendency to move patients from hospital to home at an earlier stage will continue to increase dramatically within the next decade and that you need reliable partners to help deliver high value quality and service for you and your patients.



CHALLENGES IN TREATMENT CONTINUATION (HOME SETTING)

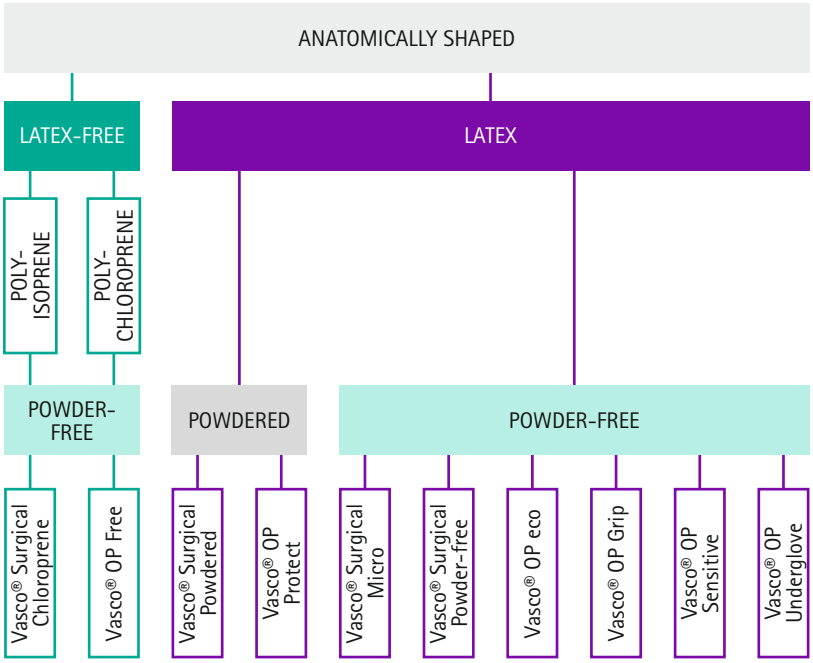
With an ageing population, more people living with complex health conditions and an overall increase in acute-care admission rates, hospitals are facing a range of challenges in organising the discharge of patients in a safe, timely and personalised manner.

The investigation of quality of care from the patient's perspective of home healthcare represents a challenge due to the multidisciplinary nature of home healthcare services and because users are often in vulnerable circumstances and it is more difficult to observe them than in a hospital ward or other health facilities.

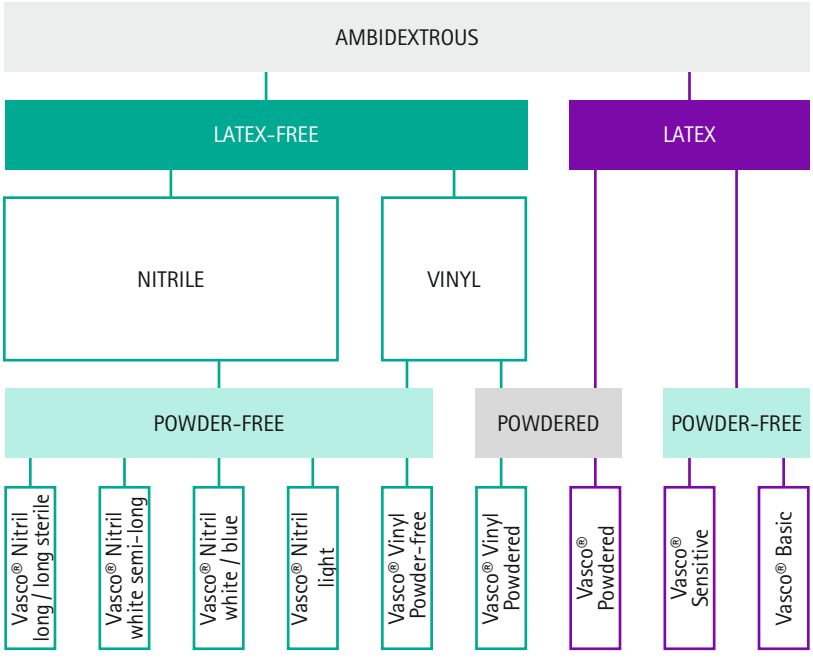
PORTFOLIO OVERVIEW

GLOVES – STERILE AND NON-STERILE

Surgical gloves (sterile)



Examination and protective gloves (non-sterile)



HAND HYGIENE AND DISINFECTION

Softasept® N	Description	Coloration	Vol. (ml)	Units per box	Code no. (REF)
	▪ For skin disinfection before surgical procedures, punctures, injections, venipunctures, and vaccinations	Colorless	250	–	local
			1,000		
			5,000		
		Colored	250		
			1,000		
			5,000		

Softa-Man® ViscoRub	Description	Vol. (ml)	Units per box	Code no. (REF)
	▪ For hygienic and surgical hand disinfection	100	-	19158
		500		19159
		1,000		19160

SURFACE DISINFECTION

Softa® Cloth CHX 2 %	Description	Content	Units per box	Code no. (REF)
	▪ Ready-to-use tissues with 70% isopropyl alcohol (IPA) and 2% chlorhexidine (CHX) ▪ For surface disinfection of medical devices ▪ Ready-to-use wipes (unfolded 162 x 150 mm) ▪ Convenient	100 wipes	1	19581

For more information on the references available in your country, please contact your local B. Braun representative.
Cautions: Use disinfectants safely. Always read the label and the product information before use. Keep away from children.

PROTECTIVE WEAR

Surgical caps	Product	Description	Color code	Units per box	Code no. (REF)
	Astron doctor's cap	▪ Non woven polypropylene		100	6111500
	Univers doctor's cap				6111501
	Adretta Comfort bouffant cap				6111502
	Adretta Basic bouffant cap				6111503
					6111504

PORTFOLIO OVERVIEW

PROTECTIVE WEAR

Visma® surgical face masks	Product	Description	Units per box	Code no. (REF)
	Visma® ear-loop	▪ Surgical face mask type II according EN 14683 ▪ Bacterial filtration efficiency (BFE) </= 98 % ▪ Breathing resistance < 29.4 Pac / cm^2 ▪ Non woven latex-free material	50	6120600
	Visma® tie-on			6120601

DRESSINGS

Sterile skin closure strips	Product	Size (mm)	Units per box	Code no. (REF)
	Askina® Strip	3 x 76	12	9084053
		6 x 76		9084061
		6 x 38		9084070
		3 x 76	50	9084002
		6 x 76		9084010
		6 x 38		9084029
		12 x 102		9084045

Askina Secure® IV	Description	Size (cm)	Units per box	Code no. (REF)
	▪ Transparent IV dressing with three securement strips	7 x 9	200 (4 boxes/50 pcs.)	5557950

DRESSINGS

Askina®	Product	Size (cm)	Units per box	Code no. (REF)
	Askina® Soft sterile	7.5 x 5	50	9086480
		9 x 5		9086501
		9 x 10		9086510
		9 x 15	40	9086528
		9 x 20	30	9086536
		9 x 25		9086544
		9 x 30		9086552
	Askina® Derm	6 x 7	5	F72031
			100	F72033
		10 x 12	5	F72034
			50	F72036
		15 x 20	10	F72038
	Askina® Pad S	5 x 5	30	9024050
		7.5 x 7.5		9024069

PORTFOLIO OVERVIEW

DRUG ADMIXTURE DEVICES

Mini-Spike® 2	Air filter	Particle filter	Units per box	Code no. (REF)
	0.45 µm	–	50	4550590

Mini-Spike® 2 Filter	Air filter	Particle filter	Units per box	Code no. (REF)
	0.45 µm	5 µm	50	4550591

LUER ACCESS DEVICE

Caresite®	Description	Priming volume (ml)	Latex-free	DEHP-free	Units per box	Code no. (REF)
	Luer Access Device	0.22	■	■	100	415122-01

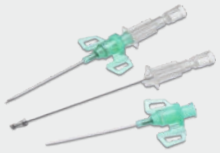
PRE-FILLED FLUSH SYRINGES AND DISINFECTION CAPS

Omniflush® with SwabCap®	Description	Volume	Units per box	Code no. (REF)
	Omniflush® with SwabCap® 10 ml in 10 ml	10 ml 0.9 % sodium chloride (NaCl)	100	EM-3513576SC
	Omniflush® with SwabCap® 5 ml in 10 ml	5 ml 0.9 % sodium chloride (NaCl)		EM-3513575SC
	Omniflush® with SwabCap® 3 ml in 10 ml	3 ml 0.9 % sodium chloride (NaCl)		EM-3513572SC

IV SOLUTIONS CONTAINER

Ecoflac® plus	Additional information	Vol. (ml)	Units per box	Code no. (REF)
	Not all IV solutions in Ecoflac® are registered and available for sales in all countries. For more information about the products available in Ecoflac® plus in your country, please contact your local B. Braun representative.	50	20	local
		100	20	
		250	10	
		500	10	
		1,000	10	

IV CATHETERS AND SECUREMENT DEVICES

Introcan Safety® 3	Gauge	Catheter length (inch)	Catheter length (mm)	Catheter ø (mm)	Flow rate (ml / min)	Units per box	Code no. (REF)
	24	¾	19	0.7	22	50	4251127-01
	22	1	25	0.9	35		4251128-01
	20	1	25	1.1	65		4251129-01
	20	1¼	32	1.1	60		4251130-01
	20	2	50	1.1	55		4251137-01
	18	1¼	32	1.3	105		4251131-01
	18	1¾	45	1.3	100		4251132-01
	16	1 1/4	32	1.7	195		4251136-01
	16	2	50	1.7	185		4251133-01

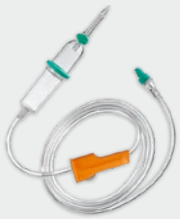
MEDICAL WASTE DISPOSAL

Sharps container

Medibox®	Description	Volume (L)	Units per box	Code no. (REF)
	According ISO 23907 2012 (sharps injury protection – requirements and test methods – sharps containers)	0.7	10	9193405
		3	10	9193413
		5	10	9193421

PORTFOLIO OVERVIEW

IV SETS

Intrafix® SafeSet	Product	Description	Length (cm)	PVC-free	Latex-free	Units per box	Code no. (REF)
	Intrafix® SafeSet	▪ AirStop and PrimeStop ▪ Pressure infusion	180	–	■	100	4063000
	Intrafix® SafeSet		230	–	■		4063003
	Intrafix® SafeSet B.C.V.	▪ AirStop and PrimeStop ▪ Infuvalve® B.C.V. (Back Check Valve) ▪ Pressure infusion	180	–	■		4063001
	Intrafix® SafeSet N.T.P.	▪ AirStop and PrimeStop ▪ Neutrapur® tubing ▪ Gravity infusion	180	■	■		4063002
	Intrafix® SafeSet Eurofix® I.S.	▪ AirStop and PrimeStop ▪ Injection site, with grip plate ▪ Pressure infusion	180	–	■		4063005
	Intrafix® SafeSet Y-N.F. Caresite®	▪ AirStop and PrimeStop ▪ Y-injection site (Caresite® needle-free valve) ▪ Pressure infusion	210	–	■		4063004C
	Intrafix® SafeSet Y-N.F. Safeflow	▪ AirStop and PrimeStop ▪ Y-injection site (Safeflow® needle-free valve) ▪ Pressure infusion	210	–	■		4063004
	Intrafix® SafeSet 3-W.S.C.	▪ AirStop and PrimeStop ▪ With 3-way stopcock ▪ Pressure infusion	220	–	■		4063006
	Intrafix® SafeSet UV-Protect	▪ AirStop and PrimeStop ▪ Transparent UV protection ▪ Gravity infusion	180	■	■		4063131
	Intrafix® SafeSet Piggyback	▪ AirStop and PrimeStop ▪ Piggyback line with B.C.V. ▪ Pressure infusion	75	■	■		4062878

B. BRAUN SOFTWARE

The software is downloadable from the internet and will need an internet access in order to work with it.

For more information please ask your B. Braun representive.

ACCESSORIES

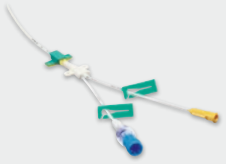
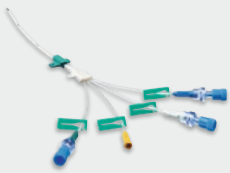
Backpack	Description	Type	Units	Code no. (REF)
	▪ Backpack for mobile Nutrition and Infusion Therapy ▪ Mobile pumps can be stowed	Curlin	1	T-1001-DE
		CADD		21-2169-25
		Extra large HPN backpack		HPN222491

PORTFOLIO OVERVIEW
PARENTERAL NUTRITION

ACCESS PORTS

Celsite® Safety	Material	Type	Units per box	Code no. (REF)
	Silicone	SST6605G 10F Si	1	4437822

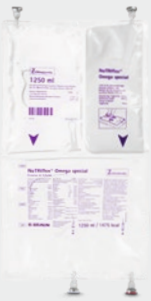
CENTRAL VENOUS CATHETERS

Certofix® protect	Product	Cath. lumen ø G	Flow rate (ml/min) *	Length (cm)	Guide wire length (cm)	Units per CAR	Code no. (REF)
	Description: with Scalpel and Safsite® Valve						
	Duo V 715 Protect	16/16	D 60; P 50	15	50		4166159P
	Duo V 720 Protect	16/16	D 55; P 45	20	50		4161211P
	Duo V 730 Protect	16/16	D 52; P 37	30	70		4161319P
	Duo HF V 720 Protect	14/18	D 100; P 27	20	50		4168534P
	Trio V 715 Protect	16/18/18	D 50; M1 28; P 28	15	50		4162153P
	Trio V 720 Protect	16/18/18	D 46; M1 22; P 22	20	50		4163214P
	Trio V 730 Protect	16/18/18	D 38; M1 18; P 18	30	70	10	4163311P
	Trio HF V 1220 Protect	16/12/12	D 55; M1 165; P 165	20	50		4160622P
	Quattro V 815 Protect	14/18/18/16	D 50; M1 20; M2 20; P 50	15	50		4167767P
	Quattro V 820 Protect	14/18/18/16	D 40; M1 15; M2 15; P 40	20	50		4167775P
	Quattro V 830 Protect	14/18/18/16	D 35; M1 10; M2 10; P 35	30	70		4167783P
	Quinto V 1220 Protect	16/18/18/18/12	D 55; M1 28; M2 28; M3 28; P 185	20	50		4166868P

*D (distal); M1 (middle1); M2 (middle2); M3 (middle3); P (proximal)

The base material of the central venous catheter Certofix® protect is polyurethane (PUR). All lumens, including the hub and the outer surface of the catheter, are embedded with a long-chain polymer based on methacrylate. Catheter material includes also hydrophilic side groups such as polyethylene glycol and antiseptic polymeric biguanide.

3-CHAMBER-BAGS

NuTRIflex® Omega	Composition 1,250 ml	NuTRIflex® Omega plus	NuTRIflex® Omega special	Units per CAR	Code no. (REF)
	Amino acids (g)	48	70.1	5	local
	Nitrogen (g)	6.8	10.0		
	Glucose (g)	150	180		
	Lipid emulsion (g):	50	50		
	▪ Medium-chain triglycerides (g)	25	25		
	▪ Soybean oil (LCT) (g)	20	20		
	▪ Omega-3 acid triglycerides (g)	5	5		
	Total energy (kcal/kJ)	1,265/5,300	1,475/6,175		
	Electrolytes (mmol)				
	Sodium (Na^+)	50	67		
	Potassium (K^+)	35	47		
	Magnesium (Mg^{2+})	4	5.3		
	Calcium (Ca^{2+})	4	5.3		
	Phosphat	15	20		
	Chloride (Cl^-)	45	60		
	Acetate	45	60		
	Zinc (Zn^{2+})	0.03	0.04		
	Volumes* (ml)	1,250; 1,875; 2,500	625; 1,250; 1,875; 2,500		

Antioxidant: Additional Vitamin E inside

* May differ from country to country

PORTFOLIO OVERVIEW
PARENTERAL NUTRITION

SINGLE NUTRIENTS

Lipofundin® MCT/LCT**	Composition 1,000 ml	Lipofundin® MCT/LCT 10%	Lipofundin® MCT/LCT 20%	Units per CAR	Code no. (REF)
	Soybean oil (LCT) (g)	50	100	10	local
	MCT oil (coconut) (g)	50	100		
	Total energy (kcal)	1,035	1,935		
	Volume* (ml)	100; 250; 500	100; 250; 500		

* May differ from country to country; ** Trade name in some countries: Medialipide®, Vasolipid®

Lipoplus®/Lipidem®**	Composition 1,000 ml		Units per CAR	Code no. (REF)
	Soybean oil (LCT) (g)	80	10	local
	MCT oil (coconut) (g)	100		
	Omega-3 acid triglycerides (g)	20		
	Total energy (kcal)	1,910		
	Volume* (ml)	100; 250; 500		

* May differ from country to country; ** Lipoplus® 200 mg/ml emulsion for infusion in some countries is called Lipidem® emulsion for infusion

Glucose	Composition 1,000 ml	Glucose 20%	Glucose 40%	Glucose 50%	Units per CAR	Code no. (REF)
	Glucose (g)	200	400	500	Ecoflac® Plus: 10 x 500 ml	local
	Energy (kcal)	800	1,600	2,000		
	Volume* (ml)		500 (Ecoflac® Plus) 500 (glass bottle)		Glass bottle: 10 x 500 ml	

* May differ from country to country

SINGLE NUTRIENTS

Aminoplasmal®	Composition 1,000 ml	Aminoplasmal® B. Braun 5% E	Aminoplasmal® B. Braun 10%	Aminoplasmal® 15%	Units per CAR	Code no. (REF)
	Amino acids (g)	50	100	150	10 x 250 ml 10 x 500 ml 6 x 1,000 ml	local
	Nitrogen (g)	7.9	15.8	24		
	Energy (kcal)	200	400	600		
	Electrolytes (mmol/l)					
	Acetate	35	28	-		
	Citrate	1.0-2.0	1.0-2.0	-		
	Sodium (Na^+)	50	-	5.3		
	Potassium (K^+)	25	-	-		
	Magnesium (Mg^{2+})	2.5	-	-		
	Phosphate	10	-	-		
	Chloride (Cl^-)	45	-	-		
	Volume* (ml)	250; 500; 1,000	250; 500; 1,000	500; 1,000		

* May differ from country to country

PORTFOLIO OVERVIEW
PARENTERAL NUTRITION

MIXING BAGS

Nutrimix®	Product	Filling lines	Vol. (ml)	Units per CAR	Code no. (REF)
	Nutrimix® 3/3	3	3,000	25	2112151
	Nutrimix® 2/3	3	2,000		2112150
	Nutrimix® 1/0	0	1,000		2112147
	Nutrimix® 0.5/0	0	500		2112146
	Nutrimix® 0.2/0	0	200		2112145

SINGLE NUTRIENTS

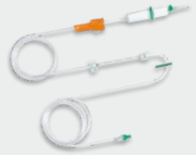
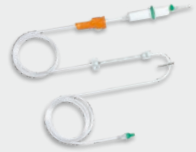
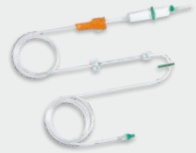
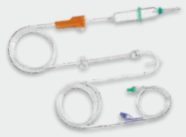
Tracutil	Composition	µg/10 ml	µmol/10 ml	Units per box	Code no. (REF)
	Iron	2,000	35	10 x 5	local
	Zinc	3,300	50		
	Manganese	550	10		
	Copper	760	12		
	Chromium	10	0.2		
	Molybdenum	10	0.1		
	Selenium	24	0.3		
	Fluoride	570	30		
	Iodide	127	1.0		
	Volume* (ml)		10 (Ampoule)		

* May differ from country to country

IV CONTAINERS

Mini-Plasco® connect	Additional information	Vol. (ml)	Units per box	Code no. (REF)
	Not all products are registered and available for sales in all countries. For more information about the products available in Mini-Plasco® connect in your country, please contact your local B. Braun representative.	5	20	local
		10		
		20		

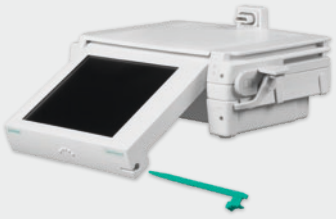
APPLICATION SETS

Infusomat® Space Lines Type SafeSet	Description	DEHP-free	Neutrapur (PVC-free)	Length (cm)	Units per box	Code no. (REF)
	▪ AirStop ▪ PrimeStop	■	–	250	100	8701148SP
	▪ AirStop ▪ PrimeStop	■	■	250		8701149SP
	▪ AirStop ▪ PrimeStop ▪ Longer tube	■	–	300		8270358SP
	▪ AirStop ▪ PrimeStop ▪ Needle-free Safeflow injection port	■	■	300		8700118SP

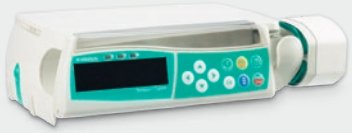
PORTFOLIO OVERVIEW
PARENTERAL NUTRITION

INFUSION PUMPS

Infusomat® Space	Description	Units per box	Code no. (REF)
	▪ **Type of unit:** Volumetric infusion pump ▪ **Dimensions:** 214 x 68 x 124 mm (WxHxD) ▪ **Weight:** Approx. 1.4 kg ▪ **Moisture protection:** IP 22, drip protected for horizontal usage ▪ **Display:** Backlit graphic display, ~ 40° read angle from all sides ▪ **Keypad:** Backlit keys, cell phone like cursor navigation ▪ **Flow Rates:** 0.1-1200 ml/h ▪ **Accuracy of set delivery rate:** ± 5 % according to IEC/EN 60601-2-24 ▪ **Operating Temperature:** +10° C ... + 40° C, +50° F ... +105° F ▪ **Voltage:** 11-16 V DC supplied by external Space Power Supply or by SpaceStation ▪ **Battery operating time with WiFi (Li-Ion):** Wireless active Infusomat at 100 ml/h 2 hours wireless inactive Infusomat at 100 ml/h 4 hours ▪ **Battery operating time without WiFi (NiMH):** Infusomat at 100 ml/h 4 hours	1	**Infusomat® Space** 8713050

Space GlucoseControl (SGC)	Description	Units per box	Code no. (REF)
	▪ **Space GlucoseControl System:** SGC is a decision supporting system for optimised insulin therapy consisting of SpaceControl the user interface and the SGC Module with its integrated eMPC algorithm.	1	**SpaceControl** 8713090
		1	**SGC Module** 8713584

INFUSION PUMPS

Perfusor® Space	Description	Units per box	Code no. (REF)
	▪ **Type of unit:** Infusion syringe pump, syringe driver ▪ **Dimensions:** 249 x 68 x 152 mm (WxHxD), drive parked ▪ **Weight:** Approx. 1.4 kg ▪ **Moisture protection:** IP 22, drip protected for horizontal usage ▪ **Display:** Backlit graphic display, ~ 40° read angle from all sides ▪ **Keypad:** Backlit keys, cell phone like cursor navigation ▪ **Flow Rates:** 0.01-1800 ml/h ▪ **Accuracy of set delivery rate:** ± 2 % in compliance with IEC/EN 60601-2-24 ▪ **Operating Temperature:** +5° C ... + 40° C, +41° F ... +105 °F ▪ **Voltage:** 11 - 16 V DC supplied by external Space Power Supply or by SpaceStation ▪ **Battery operating time with WiFi (Li-Ion):** Wireless active Perfusor at 25 ml/h 2.5 hours wireless inactive Perfusor at 25 ml/h 8 hours ▪ **Battery operating time without WiFi (NiMH):** Perfusor at 25 ml/h 8 hours	1	**Perfusor® Space** 8713030

PORTFOLIO OVERVIEW
ENTERAL NUTRITION

POLYURETHANE FEEDING TUBES

Nutritub®	Description	CH	Length (cm)	Mandarin/ Stylet (M)	Units per CAR	Code no. (REF)
	For naso-gastric and nasointestinal tube feeding. All Nutritub feeding tubes have a male ENFit™ connection only connectable with female ENFit™. ▪ Made of soft polyurethane, flexible, without DEHP ▪ Radiopaque (stripes), length markings every 10 cm allowing an easy and safe placement control ▪ Some tubes are equipped with stylet (M) ▪ Nutritub® Intestinal have weighted ends to ensure intestinal placement	**Nutritub® Naso-gastric tubes with ENFit™**				
		8	80	–	25	9246535
		10	110	■		9246512
		12	110	■		9246543
		14	110	■		9246513
		14	110	–		9246514
		16	110	■		9246515
		16	110	–		9246516
		18	110	■		9246518
		18	110	–		9246519
		Nutritub® Naso-intestinal with ENFit™				
		8	125	■	25	9246578
		12	125	■		9246586

Tubes available with ENFit™ connection in 2018.

SIP FEEDS

Nutricomp® Drink	Product	Description	Energy kcal / ml kcal / bottle (200 ml)	Units per CAR	Code no. (REF)
	Nutricomp® Drink Plus HP*	**Nutrition details** (per 100 ml): ▪ 10 g (Protein) / 27 % (Energy) ▪ 5.5 g (Fat) / 33 % (Energy) ▪ 14.3 g (Carbohydrates) / 40 % (Energy) ▪ 0 g (Fiber) **Indications** (examples): ▪ Patients at risk of malnutrition ▪ Protein-Energy malnutrition (PEM) ▪ Pre- and post-operative nutrition	1.5 kcal / ml 300 kcal		local
	Nutricomp® Drink 2.0 kcal Fibre*	**Nutrition details** (per 100 ml): ▪ 9 g (Protein) / 18 % (Energy) ▪ 8.7 g (Fat) / 36 % (Energy) ▪ 21.4 g (Carbohydrates) / 43 % (Energy) ▪ 2.5 g (Fiber) / 3 % (Energy) **Indications** (examples): ▪ Patients at risk of malnutrition ▪ Bowel fistulae ▪ Dysphagia	2 kcal / ml 400 kcal		local

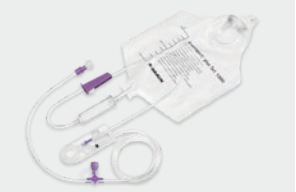
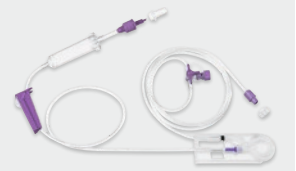
* available in 2018; ** available in 500 ml

TUBE FEEDS

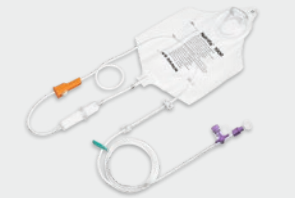
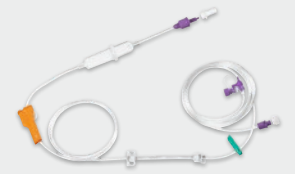
Nutricomp®	Product	Description	Units per CAR	Code no. (REF)
	High energy and protein needs			
	Nutricomp® Energy HP	**Nutrition details** (per 1,000 ml): ▪ 1,500 kcal ▪ 75 g (Protein) / 20 % (Energy) ▪ 50 g (Fat) / 30 % (Energy) ▪ 188 g (Carbohydrates) / 50 % (Energy) ▪ 0 g (Fiber) ▪ 760 ml (Water) **Indications** (examples): ▪ Chronic wasting diseases ▪ Surgery ▪ Contraindications to fiber ▪ Fluid restrictions	Bags: 15 x 500 ml HDPE Bottles: 12 x 500 ml	local
	Nutricomp® Energy HP Fibre	**Nutrition details** (per 1,000 ml): ▪ 1,560 kcal ▪ 75 g (Protein) / 20 % (Energy) ▪ 50 g (Fat) / 29 % (Energy) ▪ 188 g (Carbohydrates) / 48 % (Energy) ▪ 20 g (Fiber) / 3 % (Energy) ▪ 760 ml (Water) **Indications** (examples): ▪ Fluid restrictions ▪ Chronic wasting diseases ▪ Surgery ▪ Regulation of bowel function	Bags: 15 x 500 ml HDPE Bottles: 12 x 500 ml	local
	Disease specific diet			
	Nutricomp® Peptid	**Nutrition details** (per 1,000 ml): ▪ 1,000 kcal ▪ 38 g (Protein) / 14 % (Energy) ▪ 11 g (Fat) / 12 % (Energy) ▪ 188 g (Carbohydrates) / 73.5 % (Energy) ▪ <3 g (Fiber) / 0.5 % (Energy) ▪ 840 ml (Water) **Indications** (examples): ▪ Malassimilation syndrome (malabsorption and maldigestion) ▪ Pancreas failure ▪ Jejunal feeding	Bags: 15 x 500 ml HDPE Bottles: 12 x 500 ml	local

PORTFOLIO OVERVIEW
ENTERAL NUTRITION

APPLICATION SETS

Enteroport® plus	Product	Description	Units per CAR	Code no. (REF)
	Enteroport® plus Set 1000 ml ENFit™	▪ With 1,000 ml storage bag ▪ Graduated scale and label for patient data ▪ Roller clamp and drip chamber ▪ Stopcock with male ENFit™ connector ▪ Patient connector with female ENFit™ connector	30	8721737
	Enteroport® plus Set Universal Adapter ENPlus / ENFit™	▪ ENPlus Port in Universal Adapter (Art. no. 8721747) ▪ With ENPlus Spike ▪ Roller clamp and drip chamber ▪ Stopcock with male ENFit™ connector ▪ Patient connector with female ENFit™ connector ▪ Connection to bag systems, crown-cork and wideneck bottles, syringes and empty bags		8721747
	Enteroport® plus Set ENPlus / ENFit™			8721749

All enteral nutrition application sets are DEHP-free.

Infusomat® Space Line	Product	Description	Units per CAR	Code no. (REF)
	Infusomat® Space Line 1000 ml Type Enteral Nutrition ENFit™	▪ With 1,000 ml storage bag ▪ Graduated scale and label for patient data ▪ Roller clamp and drip chamber ▪ Stopcock with male ENFit™ connector ▪ Patient connector with female ENFit™ connector	25	8250830SP
	Infusomat® Space Line Universal Adapter Type Enteral Nutrition ENPlus/ENFit™	▪ ENPlus Port in Universal Adapter (Art. no. 8250832SP) ▪ With ENPlus Spike ▪ Roller clamp and drip chamber ▪ Stopcock with male ENFit™ connector ▪ Patient connector with female ENFit™ connector ▪ Connection to bag systems, crown-cork and wideneck bottles, syringes and empty bags	40	8250832SP
	Infusomat® Space Line Type Enteral Nutrition ENPlus/ ENFit™			8250834SP

All enteral nutrition application sets are DEHP-free.

ENTERAL PUMP

Enteroport® plus pump	Description	Units per box	Code no. (REF)
	▪ **Dimensions** (W x H x D): 14 x 4.5 x 11.5 cm ▪ **Weight:** 450 g ▪ **Battery life**: 35 h at 200 ml/h ▪ **Recharging time:** 3.5 h ▪ **Feeding program:** continuous / interval / bolus feeding ▪ **Application rate:** 1 - 400 ml/h, increments of 1 ml/h ▪ **Total volume:** 1 – 5,000 ml/h, increments of 1 ml/h (1-49 ml) and 50 ml/h (50-5,000 ml) ▪ **Bolus/interval volume:** 1 – 1,000 ml, increments of 1 l/h (1-49 ml) and 50 ml/h (50-5,000 ml) ▪ **Flow time:** 15 min - 24 h, variable at 15 min intervals ▪ **Flow rate accuracy:** +/- 10 % ▪ **Water protection:** IP 22 ▪ **Occlusion detect. pressure:** < 150 kPa (1,5 bar) ▪ **Air detection:** > 10 mL ▪ **Operating temperature:** +5°C ... + 40°C	1	8710355

MANDATORY DRUG INFORMATION

NuTRIflex® Omega

Abbreviated mandatory drug information: NuTRIflex® Omega plus/NuTRIflex® Omega special

Emulsion for infusion

QUALITATIVE AND QUANTITATIVE COMPOSITION

mixed and ready for use in 1.250 ml

	NuTRIflex® Omega plus Emulsion for infusion	NuTRIflex® Omega special Emulsion for infusion
from the upper left-hand chamber (glucose solution)		
Glucose monohydrate	165.0 g	198.0 g
≙ anhydrous glucose	150.0 g	180.0 g
Sodium dihydrogen phosphate dehydrate	2.340 g	3.120 g
Zinc acetate dehydrate	6.58 mg	8.78 mg
from the upper right-hand chamber (fat emulsion)		
Medium-chain triglycerides	25.0 g	25.0 g
Soya-bean oil refined	20.0 g	20.0 g
Omega-3-acid triglycerides	5.0 g	5.0 g
from the lower chamber (amino acid solution)		
Isoleucine	2.82 g	4.11 g
Leucine	3.76 g	5.48 g
Lysine hydrochloride	3.41 g	4.98 g
≙ Lysine	2.73 g	3.98 g
Methionine	2.35 g	3.42 g
Phenylalanine	4.21 g	6.15 g
Threonine	2.18 g	3.18 g
Tryptophan	0.68 g	1.00 g
Valine	3.12 g	4.51 g
Arginine	3.24 g	4.73 g
Histidine hydrochloride monohydrate	2.03 g	2.96 g
≙ Histidine	1.50 g	2.19 g
Alanine	5.82 g	8.49 g
Aspartic acid	1.80 g	2.63 g
Glutamic acid	4.21 g	6.14 g
Glycine	1.98 g	2.89 g
Proline	4.08 g	5.95 g
Serine	3.60 g	5.25 g
Sodium hydroxide	0.976 g	1.464 g
Sodium chloride	0.503 g	0.473 g
Sodium acetate trihydrate	0.277 g	0.313 g
Potassium acetate	3.434 g	4.611 g
Magnesium acetate tetrahydrate	0.858 g	1.137 g
Calcium chloride dehydrate	0.588 g	0.779 g
Amino acid content (g)	48	70.1
Nitrogen content (g)	6.8	10
Carbohydrate content (g)	150	180
Lipid content (g)	50	50
Electrolytes (mmol):		
Sodium	50	67
Potassium	35	47
Magnesium	4.0	5.3
Calcium	4.0	5.3
Zinc	0.03	0.04
Chloride	45	60
Acetate	45	60
Phosphate	15	20
Energy in the form of lipid [kJ (kcal)]	1990 (475)	1990 (475)
Energy in the form of carbohydrate [kJ (kcal)]	2510 (600)	3015 (720)
Energy in the form of amino acids [kJ (kcal)]	800 (190)	1170 (280)
Non-protein energy [kJ (kcal)]	4500 (1075)	5005 (1195)
Total energy [kJ (kcal)]	5300 (1265)	6175 (1475)
pH	5.0 - 6.0	5.0 - 6.0
Osmolality [mOsm/kg]	1540	2115
Theoretical osmolarity [mOsm/l]	1215	1545

LIST OF EXCIPIENTS

Citric acid monohydrate (for pH adjustment), Egg lecithin, Glycerol, Sodium oleate, All-rac-α-Tocopherol, Sodium hydroxide (for pH adjustment), Water for injections.

THERAPEUTIC INDICATIONS

Supply of energy and essential fatty acids including omega-3 and omega-6 fatty acids, amino acids, electrolytes and fluids in the setting of parenteral nutrition of patients in states of moderate to severe catabolism when oral or enteral nutrition is impossible, insufficient or contraindicated.

CONTRAINDICATIONS

- Hypersensitivity to the active substances, to egg, fish, peanut or soya protein or to any of the excipients
- Congenital disorders of amino acid metabolism
- Severe hyperlipidaemia
- Hyperglycaemia not responding to insulin doses of up to 6 units insulin/hour
- Acidosis
- Intrahepatic cholestasis
- Severe hepatic insufficiency
- Severe renal insufficiency in absence of renal replacement therapy
- Aggravating haemorrhagic diatheses
- Acute thromboembolic events, lipid embolism

On account of its composition NuTRIflex® Omega plus/special must not be used in newborn infants, infants and toddlers under 2 years of age.

General contraindications to parenteral nutrition include:

- Unstable circulatory status with vital threat (states of collapse and shock)
- Acute phases of cardiac infarction and stroke
- Unstable metabolic condition (e.g. severe postaggression syndrome, coma of unknown origin)
- Inadequate cellular oxygen supply
- Disturbances of the electrolyte and fluid balance
- Acute pulmonary oedema
- Decompensated cardiac insufficiency.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Caution should be exercised in cases of increased serum osmolarity. Disturbances of the fluid, electrolyte or acid-base balance, must be corrected before the start of infusion. Too rapid infusion can lead to fluid overload with pathological serum electrolyte concentrations, hyperhydration and pulmonary oedema. Any sign or symptom of anaphylactic reaction (such as fever, shivering, rash or dyspnoea) should lead to immediate interruption of the infusion. The serum triglyceride concentration should be monitored when infusing Nutriflex® Omega plus/special. Depending on the patient's metabolic condition, occasional hypertriglyceridaemia may occur. If the plasma triglyceride concentration rises to above 3 mmol/l during administration of lipids, it is recommended that the infusion rate be reduced. Should the plasma triglyceride concentration remain above 3 mmol/l, the administration should be stopped until the level normalises.

Like all solutions containing carbohydrates, the administration of Nutriflex® Omega plus can lead to hyperglycaemia. The blood glucose level should be monitored. If there is hyperglycaemia, the rate of infusion should be reduced or insulin should be administered. If the patient is receiving other intravenous glucose solutions concurrently, the amount of additionally administered glucose has to be taken into account.

An interruption of administration of the emulsion may be indicated if the blood glucose concentration rises to above 14 mmol/l (250 mg/dl) during administration. Intravenous infusion of amino acids is accompanied by increased urinary excretion of the trace elements, especially copper and, in particular, zinc. This should be considered in the dosing of trace elements, especially during long-term intravenous nutrition.

Refeeding or repletion of malnourished or depleted patients may cause hypokalaemia, hypophosphataemia and hypomagnesaemia. Adequate supplementation of electrolytes according to deviations from normal values is necessary.

Nutriflex® Omega plus/special should not be given simultaneously with blood in the same infusion set due to the risk of pseudoagglutination.

Controls of the serum electrolytes, the water balance, the acid-base balance and – during long-term administration – of blood cell counts, coagulation status and hepatic function are necessary.

Substitution of electrolytes, vitamins and trace elements may be necessary as required.

As Nutriflex® Omega plus/special contains zinc and magnesium, care should be taken when it is coadministered with solutions containing these elements.

As with all intravenous solutions strict aseptic precautions are necessary for the infusion of Nutriflex® Omega plus/special.

Nutriflex® Omega plus/special is a preparation of complex composition. It is, therefore, strongly advisable not to add other solutions (as long as compatibility is not proven).

Paediatric population
There is as yet no clinical experience of the use of Nutriflex Omega plus/special in children and adolescents.

Elderly patients
Basically the same dosage as for adults applies, but caution should be exercised in patients suffering from further diseases like cardiac insufficiency or renal insufficiency that may frequently be associated with advanced age.

Patients with diabetes mellitus, impaired cardiac or renal function
Like all large-volume infusion solutions, Nutriflex® Omega plus/special should be administered with caution to patients with impaired cardiac or renal function. There is only limited experience of its use in patients with diabetes mellitus or renal failure.

Patients with impaired lipid metabolism
Nutriflex® Omega plus/special should be administered cautiously to patients with disturbances of lipid metabolism, e.g. renal insufficiency, diabetes mellitus, pancreatitis, impaired hepatic function, hypothyroidism (with hypertriglyceridaemia) and sepsis. If Nutriflex® Omega plus/special is given to patients with these conditions, monitoring of serum triglycerides is necessary. The presence of hypertriglyceridaemia 12 hours after lipid administration also indicates a disturbance of lipid metabolism.

Special warnings/precautions regarding excipients
Vitamin E (α-tocopherol) can interfere with the effect of vitamin K in clotting factor synthesis. This should be considered in patients with blood coagulation disorders or suspected vitamin K deficiency and in patients treated with coumarin anticoagulants.

FERTILITY, PREGNANCY AND LACTATION

Pregnancy
There are no or limited amount of data from the use of Nutriflex® Omega plus/special in pregnant women. Animal studies undertaken with a lipid emulsion containing twice the amount of omega-3 acid triglycerides and a correspondingly smaller amount of long-chain triglycerides as compared to Nutriflex® Omega plus/special do not indicate direct or indirect harmful effects with respect to reproductive toxicity. Parenteral nutrition may become necessary during pregnancy. Nutriflex® Omega plus/special should only be given to pregnant women after careful consideration.

Breast-feeding
Components/metabolites of Nutriflex® Omega plus/special are excreted in human milk, but at therapeutic doses no effects on the breastfed newborns/infants are anticipated. Nevertheless breast-feeding is not recommended for mothers on parenteral nutrition.

Fertility
No data available.

UNDESIRABLE EFFECTS

The following listing includes a number of systemic adverse reactions that may be associated with the use of NuTRIflex® Omega plus/special. Under the conditions of correct use, in terms of dosing, monitoring, observation of safety restrictions and instructions, most of them are rare (≥ 1/10,000 to < 1/1,000).
Undesirable effects are listed according to their frequencies as follows:

Very common:	(≥ 1/10)
Common:	(≥ 1/100 to < 1/10)
Uncommon:	(≥ 1/1,000 to < 1/100)
Rare:	(≥ 1/10,000 to < 1/1,000)
Very rare:	(< 1/10,000)
Not known:	(Frequency cannot be estimated from the available data).

Blood and lymphatic system disorders
Rare: Hypercoagulation

Immune system disorders
Rare: Allergic reactions (e.g. anaphylactic reactions, dermal eruptions, laryngeal, oral and facial oedema)

Metabolism and nutrition disorders
Very rare: Hyperlipidaemia, hyperglycaemia, metabolic acidosis, ketoacidosis.
The frequency of these undesirable effects is dose-dependent and may be higher under the condition of absolute or relative lipid overdose.

Nervous system disorders
Rare: Headache, drowsiness

Vascular disorders
Rare: Hypertension or hypotension, flush

Respiratory, thoracic and mediastinal disorders
Rare: Dyspnoea, cyanosis

Gastrointestinal disorders
Uncommon: Nausea, vomiting, loss of appetite

Skin and subcutaneous tissue disorders
Rare: Erythema, sweating

Musculoskeletal and connective tissue disorders
Rare: Pain in the back, bones, chest and lumbar region.

General disorders and administration site conditions
Rare: Elevated body temperature, feeling cold, chills;
Very rare: Fat overload syndrome

Should adverse reactions occur or should the triglyceride level rise to above 3 mmol/l during infusion, the infusion should be stopped or, if necessary, continued at reduced dosage. If the infusion is restarted, the patient should be carefully monitored, especially at the beginning, and serum triglycerides should be determined at short intervals.

Information on particular undesirable effects:
Nausea, vomiting, lack of appetite and hyperglycaemia are symptoms often related to conditions indicating parenteral nutrition or may be associated with parenteral nutrition.

Fat overload syndrome
Overdose of lipid emulsion or impaired capacity to eliminate triglycerides can lead to "fat overload syndrome". Possible signs of metabolic overload must be observed. The cause may be genetic (individually different metabolism) or the fat metabolism may be affected by ongoing or previous diseases. This syndrome may also appear during severe hypertriglyceridaemia, even at the recommended infusion rate, or in association with a sudden change in the patient's clinical condition, such as renal function impairment or infection.

The fat overload syndrome is characterised by hyperlipidaemia, fever, fat infiltration, hepatomegaly with or without icterus, splenomegaly, anaemia, leucopenia, thrombocytopenia, coagulation disorder, haemolysis and reticulocytosis, abnormal liver function tests and coma. The symptoms are usually reversible if the infusion of the fat emulsion is discontinued. Should signs of a fat overload syndrome occur, the infusion of Nutriflex® Omega plus/special should be discontinued immediately.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

MARKETING AUTHORIZATION HOLDER
B. Braun Melsungen AG, 34209 Melsungen, Germany

Last revision: 07/2015

Prescription only

Not all products are registered and approved for sale in all coutries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

Lipofundin® MCT/LCT 10 %/Lipofundin® MCT/LCT 20 %

QUALITATIVE AND QUANTITATIVE COMPOSITION

1000 ml emulsion contain	Lipofundin® MCT/LCT 10%	Lipofundin® MCT/LCT 20%
Soya-bean oil, refined	50.0 g	100.0 g
Medium-chain Triglycerides (MCT)	50.0 g	100.0 g
Essential fatty acid content per 1000 ml:		
Linoleic acid	24.0 – 29.0 g	48.0 – 58.0 g
α-Linolenic acid	2.5 – 5.5 g	5.0 – 11.0 g
List of excipients		
Glycerol	25.0 g	25.0 g
Egg lecithin	8.0 g	12.0 g
all-rac-α-Tocopherol	85 ± 20 mg/l	170 ± 40 mg/l
Sodium oleate (for pH-adjustment)		
Water for injections		
Energy		
Acidity or alkalinity, titration to pH 7.4	< 0.5 mmol/l	< 0.5 mmol/l
Theoretical osmolarity	345 mOsmo/l	380 mOsmo/l
pH:	6.5-8.5	6.5-8.5

THERAPEUTIC INDICATIONS
Energy supply including a readily utilisable lipid component (MCT). Supply of essential fatty acids as part of total parenteral nutrition

CONTRAINDICATIONS
- Hypersensitivity to egg or soya-bean protein, soya-bean or peanut products or to any of the active substances or the excipients
- Severe hyperlipidaemia
- Severe coagulopathy
- Severe hepatic insufficiency
- Intrahepatic cholestasis
- Severe renal insufficiency in absence of renal replacement therapy
- Acute thromboembolic events
- Fat embolism
- Aggravating haemorrhagic diatheses
- Metabolic acidosis

General contraindications to parenteral nutrition include:
- Unstable circulatory status with vital threat (states of collapse and shock)
- Unstable metabolic conditions (e.g. severe post-aggression syndrome, severe sepsis, coma of unknown origin)
- Acute phase of myocardial infarction or stroke
- Uncorrected disorders of fluid and electrolyte balance, such as hypokalaemia and hypotonic dehydration
- Decompensated cardiac insufficiency
- Acute pulmonary oedema

FERTILITY, PREGNANCY AND LACTATION
Pregnancy
There are no or limited amount of data from the use of Lipofundin MCT in pregnant women. Animal studies are insufficient with respect to reproductive toxicity. Parenteral nutrition may become necessary during pregnancy. Lipofundin® MCT should only be given to pregnant women after careful consideration.

Breast-feeding
Components/metabolites of Lipofundin® MCT are excreted in human milk, but at therapeutic doses no effects on the breastfed newborns/infants are anticipated. Nevertheless, breast-feeding is not recommended for mothers on parenteral nutrition.

Fertility
No data from the use of Lipofundin® MCT in humans available

UNDESIRABLE EFFECTS
The following listing includes a number of systemic adverse reactions that may be associated with the use of Lipofundin® MCT/LCT. Under the conditions of correct use, in terms of dosing, monitoring, observation of safety restrictions and instructions, most of them are very rare (< 1/10 000):

Listing of undesirable effects
Undesirable effects are listed according to their frequencies as follows:

Very common:	(≥ 1/10)
Common:	(≥ 1/100 to < 1/10)
Uncommon:	(≥ 1/1,000 to < 1/100)
Rare:	(≥ 1/10,000 to < 1/1,000)
Very rare:	(< 1/10,000)
Not known:	(Frequency cannot be estimated from the available data).

Blood and lymphatic system disorders
Very rare: Hypercoagulability
Not known: Leucopenia, thrombocytopenia

Immune system disorders
Very rare: Allergic reactions (e.g. anaphylactic reactions, dermal eruptions, laryngeal, oral and facial oedema)

Metabolism and nutrition disorders
Very rare: Hyperlipidaemia, hyperglycaemia, metabolic acidosis, ketoacidosis. The frequency of these adverse reactions is dose-dependent and may be higher under conditions of absolute or relative overdose.

Nervous system disorders
Very rare: Headache, drowsiness

Vascular disorders
Very rare: Hypertension or hypotension, flush

Respiratory, thoracic and mediastinal disorders
Very rare: Dyspnoea, cyanosis

Gastrointestinal disorders
Very rare: Nausea, vomiting, loss of appetite

Hepatobiliary disorders
Not known: Cholestasis

Skin and subcutaneous tissue disorders
Very rare: Erythema, sweating

Musculoskeletal and connective tissue disorders
Very rare: Pain in the back, bones, chest and lumbar region

General disorders and administration site conditions
Very rare: Elevated body temperature, feeling cold, chills, fat overload syndrome

If adverse reactions occur, the infusion of Lipofundin MCT/LCT must be stopped or, if necessary, continued at a reduced dosage. If the infusion is restarted, the patient must be carefully monitored, especially at the beginning, and serum triglycerides should be determined at short intervals.

Information on particular undesirable effects
Nausea, vomiting, lack of appetite and hyperglycaemia are symptoms related to conditions constituting an indication for parenteral nutrition and may sometimes be associated with parenteral nutrition.

Fat overload syndrome
Overdose of lipid emulsion or impaired capacity to eliminate triglycerides can lead to "fat overload syndrome". Possible signs of metabolic overload must be observed. The cause may be genetic (individually different metabolism) or the fat metabolism may be affected by ongoing or previous diseases. This syndrome may also appear during severe hypertriglyceridaemia, even at the recommended infusion rate, or in association with a sudden change in the patient's clinical condition, such as renal function impairment or infection.

The fat overload syndrome is characterised by hyperlipidaemia, fever, fat infiltration, hepatomegaly with or without icterus, splenomegaly, anaemia, leucopenia, thrombocytopenia, coagulation disorder, haemolysis and reticulocytosis, abnormal liver function tests and coma. The symptoms are usually reversible if the infusion of the fat emulsion is discontinued. Should signs of a fat overload syndrome occur, the infusion of Lipofundin MCT/LCT must be discontinued immediately.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

MARKETING AUTHORIZATION HOLDER
B. Braun Melsungen AG, 34209 Melsungen, Germany

Last revision: 10/2014

Prescription only.

Not all products are registered and approved for sale in all countries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

MANDATORY DRUG INFORMATION

Lipoplus®/Lipidem®

COMPOSITION
1,000 ml of emulsion contains

Medium-chain triglycerides	100.0 g
Soya-bean oil, refined	80.0 g
Omega-3-acid triglycerides	20.0 g
Essential fatty acid content per liter:	
Linoleic acid (omega-6)	38.4 - 46.4 g/l
Alpha-linolenic acid (omega-3)	4.0 - 8.8 g/l
Eicosapentaenoic acid and Docosahexaenoic acid (omega-3)	8.6 – 17.2 g/l
Caloric content per liter:	7,900 kJ ≈ 1,910 kcal
Osmolality:	approx. 410 mOsm/kg
Titration acidity or alkalinity (to pH 7.4):	less than 0.5 mmol/l NaOH or HCl
pH:	6.5 - 8.5

LIST OF EXCIPIENTS
Egg lecithin, Glycerol,Sodium oleate, Ascorbyl palmitate, all-rac-a-Tocopherol, Sodium hydroxide (for pH adjustment), Water for injections

Excipient(s) with known effect:
1,000 ml emulsion contains 2.6 mmol sodium (as sodium hydroxide and sodium oleate).

INDICATIONS
Supply of energy, including a readily utilisable lipid component (medium-chain triglycerides) and essential omega-6 fatty acids and omega-3 fatty acids, as part of parenteral nutrition when oral or enteral nutrition is impossible, insufficient or contraindicated. Lipoplus® is indicated in adults, preterm and term neonates, infants and toddlers, children and adolescents.

CONTRAINDICATIONS
- Hypersensitivity to the active substances, to egg, fish, peanut or soya protein or to any of the excipients
- Severe hypertriglyceridaemia (≥ 1000 mg/dl or 11.4 mmol/l)
- Severe coagulopathy
- Intrahepatic cholestasis
- Severe hepatic insufficiency
- Severe renal insufficiency in absence of renal replacement therapy
- Acute thromboembolic events, fat embolism
- Acidosis

General contraindications to parenteral nutrition include:
- Unstable circulatory status with vital threat (states of collapse and shock)
- Acute phases of cardiac infarction or stroke
- Unstable metabolic conditions (e. g. decompensated diabetes mellitus, severe sepsis, coma of unknown origin)
- Inadequate cellular oxygen supply
- Disturbances of the electrolyte and fluid balance
- Acute pulmonary oedema
- Decompensated cardiac insufficiency

SPECIAL WARNINGS AND PRECAUTIONS FOR USE
The serum triglyceride concentration should be monitored when infusing Lipoplus®.

In patients with suspected disorders of lipid metabolism, fasting hyperlipidaemia should be ruled out before the start of the infusion.

Depending on the patient's metabolic condition, occasional hypertriglyceridaemia may occur. If the plasma triglyceride concentration exceeds 4.6 mmol/l (400 mg/dl) in adults during administration of lipids it is recommended to reduce the infusion rate. The infusion must be interrupted if the plasma triglyceride concentration exceeds 11.4 mmol/l (1,000 mg/dl), as these levels have been associated with an increased risk for acute pancreatitis.

Disturbances of the fluid, electrolyte or acid-base balance must be corrected before the start of infusion.

Refeeding or repletion of malnourished or depleted patients may cause hypokalaemia, hypophosphataemia and hypomagnesaemia. Adequate supplementation of electrolytes according to deviations from normal values is necessary.

Controls of the serum electrolytes, the water balance, the acid-base balance, and of blood cell counts, coagulation status, hepatic and renal function are necessary.

Any sign or symptom of anaphylactic reaction (such as fever, shivering, rash or dyspnoea) should lead to immediate interruption of the infusion.

Energy supply with lipid emulsions only could cause metabolic acidosis. It is therefore recommended to infuse an adequate quantity of intravenous carbohydrates or carbohydrate-containing amino acid solutions along with the fat emulsion.

For patients requiring complete parenteral nutrition, complementary carbohydrate, amino acid, electrolyte, vitamin, and trace element supplements are required. Also, an adequate total fluid intake has to be ensured.

Impaired capacity to eliminate triglycerides can lead to "fat overload syndrome" which may be caused by overdose.

Mixing with incompatible substances might lead to breaking of the emulsion or to precipitation of particles, both resulting in a high risk of embolism.

There is as yet only limited experience of the use of Lipoplus® for periods longer than seven days. As with all intravenous solutions, especially for parenteral nutrition, strict aseptic precautions are necessary for the infusion of Lipoplus®.

Patients with diabetes mellitus, impaired cardiac or renal function
Like all large-volume infusion solutions, Lipoplus® should be administered with caution to patients with impaired cardiac or renal function. There is only limited experience of its use in patients with diabetes mellitus or renal failure.

Patients with impaired lipid metabolism
Lipoplus should be administered cautiously to patients with disturbances of lipid metabolism with increased serum triglycerides, e.g. renal insufficiency, diabetes mellitus, pancreatitis, impaired hepatic function, hypothyroidism (with hypertriglyceridaemia), sepsis, and metabolic syndrome. If Lipoplus® is given to patients with these conditions, more frequent monitoring of serum triglycerides is necessary to assure triglyceride elimination and stable triglyceride levels below 11.4 mmol/l (1,000 mg/dl). In combined hyperlipidaemias and in metabolic syndrome, triglyceride levels react to glucose, lipids and overnutrition. Adjust dose accordingly. Assess and monitor other lipid and glucose sources, and drugs interfering with their metabolism. The presence of hypertriglyceridaemia 12 hours after the administration of lipids also indicates disturbance of lipid metabolism.

Paediatric population
Free fatty acids (FFA) compete with bilirubin for albumin binding sites. Especially very premature infants may be at increased risk of hyperbilirubinaemia due to high levels of FFA released from triglycerides resulting in a high FFA/albumin ratio. In parenterally fed infants at risk of hyperbilirubinaemia, serum triglyceride and bilirubin levels should be monitored and lipid infusion rate be adjusted if deemed necessary. During infusion Lipoplus® should be protected from phototherapy light to decrease the formation of potentially harmful triglyceride hydroperoxides. The serum triglyceride concentration should be regularly monitored during the infusion of Lipoplus® (especially in very small preterm infants), especially if there is an increased risk of hyperlipidaemia (e.g. in situations of stress or infection). A stepwise increase of the daily dose may be advisable. Depending on the patient's metabolic condition, occasional hypertriglyceridaemia may occur. In infants dose reduction should be considered if the plasma triglyceride concentration during infusion exceeds 2.8 mmol/l (250 mg/dl). In older children and adolescents dose reduction should be considered if the plasma triglyceride concentration during infusion exceeds 4.6 mmol/l (400 mg/dl).

SPECIAL WARNINGS/PRECAUTIONS REGARDING EXCIPIENTS
Lipoplus® contains 2.6 mmol/l of sodium. This should be taken into consideration for patients on a controlled sodium diet.

FERTILITY, PREGNANCY AND LACTATION
Pregnancy
There are no or limited amount of data from the use of Lipoplus® in pregnant women. Animal studies undertaken with a lipid emulsion containing twice the amount of omega-3 acid triglycerides and a correspondingly smaller amount of omega-6-acid triglycerides as compared to Lipoplus® do not indicate direct or indirect harmful effects with respect to reproductive toxicity. Parenteral nutrition may become necessary during pregnancy. Lipoplus® should only be administered to pregnant women after careful benefit-risk consideration.

Breastfeeding
Components/metabolites of Lipoplus® are excreted in human milk, but at therapeutic doses of Lipoplus® no effects on the breastfed newborns/infants are anticipated. In general, breastfeeding is not recommended to mothers on parenteral nutrition.

Fertility
No data from the use of Lipoplus® available.

UNDESIRABLE EFFECTS
The following listing includes a number of systemic adverse reactions that may be associated with the use of Lipoplus®. Under the conditions of correct use, in terms of dosing, monitoring, observation of safety restrictions and instructions, most of them are very rare (< 1/10,000).

Undesirable effects are listed according to their frequencies as follows:
Very common (≥ 1/10)
Common (≥ 1/100 to < 1/10)
Uncommon (≥ 1/1,000 to < 1/100)
Rare (≥ 1/10,000 to < 1/1,000)
Very rare (< 1/10,000)
Not known (cannot be estimated from the available data)

Blood and lymphatic system disorders
Very rare: Hypercoagulation; Not known: Leucopenia, thrombocytopenia

Immune system disorders
Very rare: Allergic reactions (e.g. anaphylactic reactions, dermal eruptions, laryngeal, oral and facial oedema)

Metabolism and nutrition disorders
Very rare: Hyperlipidaemia, metabolic acidosis

The frequency of these adverse reactions is dose-dependent and may be higher under conditions of absolute or relative overdose.
Very rare: Hyperglycaemia

Nervous system disorders
Very rare: Headache, drowsiness

Vascular disorders
Very rare: Hypertension or hypotension, flush

Respiratory, thoracic and mediastinal disorders
Very rare: Dyspnoea, cyanosis

Gastrointestinal disorders
Very rare: Nausea, vomiting, loss of appetite 012

Skin and subcutaneous tissue disorders
Very rare: Erythema, sweating

Hepatobiliary disorders
Not known: Cholestasis

Musculoskeletal and connective tissue disorders
Rare: Pain in the back, bones, chest and lumbar region

General disorders and administration site conditions
Very rare: Elevated body temperature, feeling cold, chills, fat overload syndrome (see below).

Should adverse reactions occur, the infusion must be stopped.
Should the triglyceride level rise to above 11.4 mmol/l (1,000 mg/dl) during infusion, the infusion must be stopped. With levels above 4.6 mmol/l (400 mg/dl), the infusion may be continued at a reduced dosage. If the infusion is restarted, the patient should be carefully monitored, especially at the beginning, and serum triglycerides should be determined at short intervals.

Information on particular undesirable effects
Nausea, vomiting and lack of appetite are symptoms often related to conditions for which parenteral nutrition is indicated, and may be associated with parenteral nutrition at the same time.

Fat overload syndrome
Impaired capacity to eliminate triglycerides can lead to "fat overload syndrome" which may be caused by overdose. Possible signs of metabolic overload must be observed. The cause may be genetic (individually different metabolism) or the fat metabolism may be affected by ongoing or previous diseases. This syndrome may also appear during severe hypertriglyceridaemia, even at the recommended infusion rate, and in association with a sudden change in the patient's clinical condition, such as renal function impairment or infection. The fat overload syndrome is characterised by hyperlipidaemia, fever, fat infiltration, hepatomegaly with or without icterus, splenomegaly, anaemia, leucopenia, thrombocytopenia, coagulation disorder, haemolysis and reticulocytosis, abnormal liver function tests and coma. The symptoms are usually reversible if the infusion of the fat emulsion is discontinued. Should signs of a fat overload syndrome occur, the infusion of Lipoplus® must be discontinued immediately.

MARKETING AUTHORIZATION HOLDER
B. Braun Melsungen AG, 34209 Melsungen, Germany

Last revision: 03/2016

Prescription only

Not all products are registered and approved for sale in all coutries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

Glucose B. Braun 200 mg/ml Solution for Infusion

QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 1000 ml of the solution for infusion contain

Glucose monohydrate	220.0 g
≙ glucose	200.0 g
Caloric value	3350 kJ/l = 800 kcal/l
Theoretical osmolarity	1110 mOsm/l
Titration acidity (to pH 7.4)	< 1 mmol/l
pH	3.5 - 5.5

LIST OF EXCIPIENTS
Hydrochloric acid (for pH adjustment), Water for injections

THERAPEUTIC INDICATIONS
- Administration of glucose for caloric support
- Carbohydrate component in parenteral nutrition regimens
- Therapy of hypoglycaemia

CONTRAINDICATIONS
- Hyperglycaemia, not responding to insulin doses of up to 6 units insulin/hour
- Delirium tremens if such patients are already dehydrated
- Acute states of shock and collapse
- Metabolic acidosis
- Hyperhydration
- Pulmonary oedema
- Acute cardiac failure

UNDESIRABLE EFFECTS
Provided the product is used in accordance with the directions given in the SmPC, undesirable effects are not to be expected.

Paediatric population:
No special features.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

MARKETING AUTHORIZATION HOLDER
B. Braun Melsungen AG, 34209 Melsungen, Germany

Last revision: 09/2014

Prescription only

Not all products are registered and approved for sale in all coutries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

Glucose B. Braun 400 mg/ml Solution for Infusion

QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 1000 ml of the solution for infusion contain

Glucose monohydrate	440.0 g
≙ glucose	400.0 g
Caloric value	6700 kJ/l = 1600 kcal/l
Theoretical osmolarity	2220 mOsm/l
Titration acidity (to pH 7.4)	< 1 mmol/l
pH	3.5 - 5.5

LIST OF EXCIPIENTS
Hydrochloric acid (for pH adjustment), Water for injections

THERAPEUTIC INDICATIONS
- Administration of glucose for caloric support
- Carbohydrate component in parenteral nutrition, especially in high-caloric nutrition regimens or in cases where fluid intake has to be restricted
- Therapy of hypoglycaemia

CONTRAINDICATIONS
- Hyperglycaemia, not responding to insulin doses of up to 6 units insulin/hour
- Delirium tremens if such patients are already dehydrated
- Acute states of shock and collapse
- Metabolic acidosis
- Hyperhydration
- Pulmonary oedema
- Acute cardiac failure

UNDESIRABLE EFFECTS
Provided the product is used in accordance with the directions given in the SmPC, undesirable effects are not to be expected.

Paediatric population:
No special features.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

MARKETING AUTHORIZATION HOLDER
B. Braun Melsungen AG, 34209 Melsungen, Germany

Last revision: 09/2014

Prescription only

Not all products are registered and approved for sale in all coutries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

Glucose B. Braun 500 mg/ml Solution for Infusion

QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 1000 ml of the solution for infusion contain

Glucose monohydrate	550.0 g
≙ glucose	500.0 g
Caloric value	8375 kJ/l = 2000 kcal/l
Theoretical osmolarity	2770 mOsm/l
Titration acidity (to pH 7.4)	< 1.5 mmol/l
pH	3.5 - 5.5

LIST OF EXCIPIENTS
Hydrochloric acid (for pH adjustment), Water for injections

THERAPEUTIC INDICATIONS
- Administration of glucose for caloric support
- Carbohydrate component in parenteral nutrition, especially in high-caloric nutrition regimens or in cases where fluid intake has to be restricted
- Therapy of hypoglycaemia

CONTRAINDICATIONS
- Hyperglycaemia, not responding to insulin doses of up to 6 units insulin/hour
- Delirium tremens if such patients are already dehydrated
- Acute states of shock and collapse
- Metabolic acidosis
- Hyperhydration
- Pulmonary oedema
- Acute cardiac failure

UNDESIRABLE EFFECTS
Provided the product is used in accordance with the directions given in the SmPC, undesirable effects are not to be expected.

Paediatric population:
No special features.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

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MANDATORY DRUG INFORMATION

Aminoplasmal B.Braun 10% / Aminoplasmal 15% / Aminoplasmal B.Braun 5% E

Solution for Infusion

QUALITATIVE AND QUANTITATIVE COMPOSITION
1,000 ml of solution contain

	Aminoplasmal B.Braun 10%	Aminoplasmal 15%	Aminoplasmal B.Braun 5% E
Isoleucine	5.00 g	5.850 g	2.50 g
Leucine	8.90 g	11.400 g	4.45 g
Lysine monohydrate	3.12 g	8.930 g	-
≙ Lysine	(2.78 g)	(7.950 g)	-
Lysine hydrochloride	-	-	4.28 g
≙ Lysine	-	-	(3.43 g)
Lysine acetate	5.74 g	-	-
≙ Lysine	(4.07 g)	-	-
Methionine	4.40 g	5.700 g	2.20 g
Phenylalanine	4.70 g	5.700 g	2.35 g
Threonine	4.20 g	5.400 g	2.10 g
Tryptophan	1.60 g	2.100 g	0.80 g
Valine	6.20 g	7.200 g	3.10 g
Arginine	11.50 g	16.050 g	5.75 g
Histidine	3.00 g	5.250 g	1.50 g
Alanine	10.50 g	22.350 g	5.25 g
Glycine	12.00 g	19.200 g	6.00 g
Aspartic acid	5.60 g	7.950 g	2.80 g
Glutamic acid	7.20 g	16.200 g	3.60 g
Proline	5.50 g	7.350 g	2.75 g
Serine	2.30 g	3.000 g	1.15 g
Tyrosine	0.40 g	0.500 g	0.40 g
Acetylcyteine	-	0.500 g	-
≙ Cystein	-	(0.370 g)	-
Sodium acetat trihydrate	-	-	1.361 g
Potassium acetate	-	-	2.453 g
Sodium chloride	-	-	0.964 g
Sodium hydroxide	-	-	0.140 g
Sodium dihydrogen phosphate dihydrate	-	-	-
Magnesium chloride hexahydrate	-	-	0.508 g
Disodium phosphate dodecahydrate	-	-	3.581 g
Magnesium acetate tetrahydrate	-	-	-
Electrolyte concentrations			
Acetate	28 mmol/l	-	35 mmol/l
Citrate	1.0-2.0 mmol/l	-	1.0-2.0 mmol/l
Sodium	-	5.3 mmol/l	50 mmol/l
Potassium	-	-	25 mmol/l
Magnesium	-	-	2.5 mmol/l
Phosphate	-	-	10 mmol/l
Chloride	-	-	45 mmol/l
Total amino acids	100 g/l	150 g/l	50 g/l
Total nitrogen	15.8 g/l	24.0 g/l	7.9 g/l

Aminoplasmal 15%:
Excipient with known effect:
This medicinal product contains 5.3 mmol sodium per 1,000 ml.
To be taken into consideration in patients on a controlled sodium diet.

LIST OF EXCIPIENTS
Aminoplasmal 15%:
Sodium Hydroxide, Citric acid monohydrate (for pH adjustment), Water for injections

Aminoplasmal B.Braun 10% / Aminoplasmal B.Braun 5% E:
Acetylcysteine, Citric acid monohydrate (for pH adjustment), Water for injections

THERAPEUTIC INDICATIONS
Aminoplasmal B.Braun 10% / Aminoplasmal 15%:
Supply of amino acids for parenteral nutrition, when oral or enteral nutrition is impossible, insufficient or contraindicated. For adults, adolescents and children over 2 years of age.

Aminoplasmal B.Braun 5% E:
Supply of amino acids and a limited amount of electrolytes for parenteral nutrition, when oral or enteral nutrition is impossible, insufficient or contraindicated. For adults, adolescents and children over 2 years of age.

CONTRAINDICATIONS
- Hypersensitivity to the active substances or to any of the excipients
- Inborn errors of amino acid metabolism
- Severe circulation disorders with vital risk (e.g. shock)
- Hypoxia
- Metabolic acidosis
- Severe hepatic insufficiency
- Severe renal insufficiency in absence of renal replacement therapy
- High and uncorrected plasma concentration of one of the electrolytes contained in the product (Aminoplasmal B.Braun 5% E)
- Decompensate cardiac insufficiency
- Acute pulmonary oedema
- Disturbances of the electrolyte and fluid balance

The medicinal product must not be administered to newborn infants, infants and toddlers less than two years of age, because the amino acid composition do not properly meet the special requirements of this paediatric age group.

UNDESIRABLE EFFECTS
Undesirable effects that, however, are not specifically related to the product but to parenteral nutrition in general may occur, especially at the beginning of parenteral nutrition.
Undesirable effects are listed according to their frequencies as follows:

Common:	≥ 1/10	
Uncommon:	≥ 1/100	to < 1/10
Rare:	≥ 1/1,000	to < 1/100
Very rare:	≥ 1/10,000	to < 1/1,000
Not known:		< 1/10,000

Immune system disorders:
Not known: Allergic reactions
Gastrointestinal disorders:
Uncommon: Nausea, vomiting
General disorders and administration site conditions
Uncommon: Headache, elevated body temperature, chills
General disorders and administration site conditions (Aminoplasmal B.Braun 5% E)
Uncommon: Headache, chills, fever
Only Aminoplasmal B.Braun 5% E:
Not known: Local reactions at infusion site, including local pain, venous irritation and occasionally thrombophlebitis.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

MARKETING AUTHORIZATION HOLDER
B.Braun Melsungen AG, 34209 Melsungen, Germany

Last revision: 02/2015

Prescription only

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Tracutil Concentrate for Solution for Infusion

QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 1 ml of the concentrate for solution for infusion contains

Ferrous chloride	695.8 micrograms
Zinc chloride	681.5 micrograms
Manganese chloride	197.9 micrograms
Cupric chloride (USP)	204.6 micrograms
Chromic chloride (USP)	5.3 micrograms
Sodium selenite pentahydrate	7.89 micrograms
Sodium molybdate dihydrate	2.42 micrograms
Potassium iodide	16.6 micrograms
Sodium fluoride	126.0 micrograms

Thus, each one ampoule of 10 ml contains

Trace element		
Iron	35 micromol	2000 micrograms
Zinc	50 micromol	3300 micrograms
Manganese	10 micromol	550 micrograms
Copper	12 micromol	760 micrograms
Chromium	0.2 micromol	10 micrograms
Selenium	0.3 micromol	24 micrograms
Molybdenum	0.1 micromol	10 micrograms
Iodine	1.0 micromol	127 micrograms
Fluorine	30 micromol	570 micrograms

Excipient with known effect:
Each 10 ml-ampule contains 147 micromol (or 3.4 mg) sodium.

LIST OF EXCIPIENTS
Hydrochloric acid, Water for injections

THERAPEUTIC INDICATIONS
Tracutil is used as part of intravenous nutrition providing a source of trace elements for adult patients.

CONTRAINDICATIONS
- Hypersensitivity to any of the ingredients of Tracutil.
- Pronounced cholestasis (serum bilirubin > 140 mmol/l and elevated levels of gammaglutamyltransferase and alkaline phosphatase)
- Wilson's disease and disturbed iron storage (i.e. haemosiderosis or haemochromatosis).

Tracutil must not be administered to newborn infants, infants and children, because the composition does not meet the special requirements of this age group.

UNDESIRABLE EFFECTS
Immune system disorder
Not known: Anaphylactic reactions to parenterally administered iron, with possible fatal outcome.
Iodine may cause allergic reactions.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

MARKETING AUTHORIZATION HOLDER
B.Braun Melsungen AG, 34209 Melsungen, Germany

Last revision: 06/2013

Prescription only

Not all products are registered and approved for sale in all coutries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

Softa-Man® ViscoRub

COMPOSITION
100 ml solution contain: Active substances: 45 g ethanol (100%), 18 g 1-propanol.

OTHER INGREDIENTS
Purified water, butanone, glycerol, isopropyl myristate, cetearyl ethylhexanoate, octyl dodecanol, edetol, acrylates/C10-30 alkyl acrylate crosspolymer, (+/-)alpha bisabolol

THERAPEUTIC INDICATIONS
Hygienic and surgical hand disinfection.

CONTRAINDICATIONS
Hypersensitivity (allergy) to ethanol, 1-propanol or any of the other ingredients.

UNDESIRABLE EFFECTS
Contact allergy. Skin irritation such as redness and burning can occur, especially with frequent use.

WARNINGS
Flammable.
Keep container tightly closed.
Keep away from sources of ignition - No smoking!
Avoid contact with eyes. Do not use on injured skin or mucous membranes.
For external use only.
Flash point 21°C per DIN 51755.

MARKETING AUTHORIZATION HOLDER
B. Braun Melsungen AG, 34209 Melsungen, Germany

Last revision: 02/2012

Prescription only

Not all products are registered and approved for sale in all coutries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

Softasept® N /Softasept® N coloured

COMPOSITION
100 g solution contain

ACTIVE SUBSTANCES
74.1 g ethanol and 10.0 g isopropyl alcohol.

OTHER INGREDIENTS
Purified water, (Softasept® N coloured also contains povidone, citric acid monohydrate, dyes C.I. 15985 [E 110] and C.I. 14720 [E 122]).

THERAPEUTIC INDICATIONS
Skin disinfection before surgical procedures, punctures and injections.

CONTRAINDICATIONS
Hypersensitivity (allergy) to ethanol, isopropyl alcohol or (only Softasept® N coloured) any of the other ingredients. Not suited for antiseptic treatment of mucous membranes or use in the immediate vicinity of the eyes.

UNDESIRABLE EFFECTS
Contact allergy. Skin irritation such as redness and burning can occur, especially with frequent use.

Skin irritation such as redness and burning can occur, especially with frequent use. Contact allergies are also possible.

WARNINGS
Highly flammable.
Keep container tightly closed.
Keep away from sources of ignition – No smoking!
Do not spray in open flame! Avoid contact with eyes. Do not use on damaged skin or mucous membranes.
For external use only.
Flash point 14 °C per DIN 51755

MARKETING AUTHORIZATION HOLDER
B. Braun Melsungen AG, 34209 Melsungen, Germany

Last revision: 03/2011

Prescription only

Not all products are registered and approved for sale in all coutries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

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NOTES

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Date of last revision: 12.2017