NAME OF THE MEDICINAL PRODUCT

Ibuprofen B. Braun 400 mg solution for infusion
Ibuprofen B. Braun 600 mg solution for infusion

COMPOSITION

Ibuprofen B. Braun 400 mg:
1 ml of solution contains 4 mg of ibuprofen.
Each 100 ml bottle contains 400 mg of ibuprofen.

Excipient with known effect:
1 ml of solution contains 9.10 mg of sodium chloride (3.58 mg of sodium).
Each 100 ml bottle contains 910 mg of sodium chloride (358 mg of sodium).

Ibuprofen B. Braun 600 mg:
1 ml of solution contains 6 mg of ibuprofen.
Each 100 ml bottle contains 600 mg of ibuprofen.

Excipient with known effect:
1 ml of solution contains 9.15 mg of sodium chloride (3.60 mg of sodium).
Each 100 ml bottle contains 915 mg of sodium chloride (360 mg of sodium).

Excipients:
L-arginine, sodium chloride, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment), water for injections.

THERAPEUTIC INDICATIONS

Ibuprofen B. Braun 400 mg solution for infusion is indicated in adults for the short-term symptomatic treatment of acute moderate pain, and for the short-term symptomatic treatment of fever, when administration by intravenous route is clinically justified, when other routes of administration are not possible.

Ibuprofen B. Braun 600 mg is indicated in adults for the short-term symptomatic treatment of acute moderate pain, when administration by intravenous route is clinically justified, when other routes of administration are not possible.

CONTRAINDICATIONS

Hypersensitivity to the active substance, to other NSAIDs or to any of the excipients.
A history of bronchospasm, asthma, rhinitis, angioedema or urticaria associated with taking acetylsalicylic acid (ASA) or other non-steroidal anti-inflammatory drugs (NSAIDs); conditions involving an increased tendency or active bleeding such as thrombocytopenia; active, or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding); history of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy; cerebrovascular or other active bleeding; severe hepatic or renal insufficiency; severe heart failure (NYHA Class IV); severe dehydration (caused by vomiting, diarrhoea or insufficient fluid intake); pregnancy, in the last trimester.

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 < 1/1000)
Very rare: (<1/10 000)
Not known: (cannot be estimated from the available data)

The most commonly observed adverse events are gastrointestinal in nature. Peptic ulcers, GI perforation or bleeding, sometimes fatal, particularly in the elderly may occur. Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease have been reported following administration. Less frequently, gastritis has been observed. Particularly the risk of gastrointestinal bleeding occurring is dependent on the dose range and the duration of use.
Very rarely have been reported severe hypersensitivity reactions (including infusion site reactions, anaphylactic shock) and serious cutaneous adverse reactions such as bullous reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis (Lyell’s syndrome), erythema multiforme and alopecia.
Exacerbation of infection-related inflammations (e.g. development of necrotising fasciitis) coinciding with the use of non-steroidal anti-inflammatory drugs has been described. This is possibly associated with the mechanism of action of the non-steroidal anti-inflammatory drugs.
Photosensitivity, allergic vasculitis and in exceptional cases, severe skin infections and soft-tissue complications may occur during a varicella infection.
Oedema, hypertension and cardiac failure have been reported in association with NSAID treatment.
Clinical studies suggest that use of ibuprofen, particularly at a high dose (2400 mg/day) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke).

System organ class

Infections and infestations
Very rare: Exacerbation of infection-related inflammations (e.g. development of necrotising fasciitis) coinciding with the use of non-steroidal anti-inflammatory drugs has been described. This is possibly associated with the mechanism of action of the non-steroidal anti-inflammatory drugs.

Blood and lymphatic system disorders
Very rare: Disturbances to blood formation (anaemia, agranulocytosis, leukopenia, thrombocytopenia, and pancytopenia). First symptoms are: fever, sore throat, superficial mouth wounds, influenza-like complaints, severe lassitude, nosebleeds and skin bleeding.

Immune system disorders
Uncommon: Hypersensitivity reactions with skin rashes and itching, as well as asthma attacks (possibly with drop in blood pressure).
Very rare: Systemic lupus erythematosus, severe hypersensitivity reactions, face-oedema, swelling of the tongue, swelling of the internal larynx with constriction of the airways, difficulty breathing, palpitations, hypotension and life-threatening (shock).

Psychiatric disorders
Uncommon: Anxiety, restlessness.
Rare: Psychotic reactions, nervousness, irritability, confusion or disorientation and depression.

Nervous System disorders
Very common: Fatigue or sleeplessness, headache, dizziness.
Uncommon: Insomnia, agitation, irritability or tiredness.
Very rare: Aseptic meningitis (stiff neck, headache, nausea, vomiting, fever or confusion).
Patients with autoimmune disorders (SLE, mixed connective-tissue disease) appear to be predisposed.

Eye disorders
Uncommon: Visual disturbances.
Rare: Reversible toxic amblyopia.

Ear and labyrinth disorders
Common: Vertigo.
Uncommon: Tinnitus.
Rare: Hearing disorders.

Cardiac disorders
Very rare: Palpitations, heart failure, myocardial infarction.

Vascular disorders
Very rare: Arterial hypertension.

Respiratory, thoracic and mediastinal disorders
Very rare: Asthma, bronchospasm, dyspnoea and wheezing.

Gastrointestinal disorders
Very common: Pyrosis, abdominal pain, nausea, vomiting, flatulence, diarrhoea, constipation and slight gastro-intestinal blood losses that may cause anaemia in exceptional cases.
Common: Gastrointestinal ulcers, potentially with bleeding and perforation. Ulcerative stomatitis, exacerbation of colitis and Crohn´s disease.
Uncommon: Gastritis.
Rare: Oesophageal stenosis, exacerbation of diverticular disease, unspecific haemorrhagic colitis. If gastrointestinal bleeding occurs could cause anaemia and haematemesis.
Very rare: Oesophagitis, pancreatitis, formation of intestinal, diaphragm-like strictures.

Hepatobiliary disorders
Rare: Jaundice, hepatic dysfunction, hepatic damage, acute hepatitis.
Not known: Hepatic insufficiency.

Skin and subcutaneous tissue disorders
Common: Skin eruption.
Uncommon: Urticaria, pruritus, purpura (including allergic purpura), skin rash.
Very rare: Bullous reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis (Lyell's syndrome), erythema multiforme, alopecia. Photosensitivity reactions and allergic vasculitis. In exceptional cases, severe skin infections and soft-tissue complications in varicella infection (see also "Infections and infestations").
Not known: Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), Acute generalised exanthematous pustulosis (AGEP).

Musculoskeletal and connective tissue disorders
Rare: Stiff neck

Renal and urinary disorders
Uncommon: Reduced urinary excretion and formation of oedemas, particularly in patients with arterial hypertension or renal insufficiency, nephrotic syndrome, interstitial nephritis that may be accompanied by acute renal insufficiency.
Rare: Renal tissue damage (papillary necrosis), particularly in long-term therapy, increased serum uric acid concentration in the blood.

General disorders and administration site conditions
Common: Pain and burning sensation in the administration site
Not known: Injection site reaction such as swelling, haematoma or bleeding.

WARNINGS

Keep out of the sight and reach of children.

NOTE

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.

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