

## **NAME OF THE MEDICINAL PRODUCT**

Fentanyl B. Braun 0.1 mg solution for injection  
Fentanyl B. Braun 0.5 mg solution for injection

## **COMPOSITION**

1 ml solution for injection contains 78.5 micrograms fentanyl citrate, equivalent to 50 micrograms fentanyl.

1 ampoule of 2 ml Fentanyl B. Braun 0.1 mg contains 100 micrograms of fentanyl, as fentanyl citrate, 157 micrograms.

1 ampoule of 10 ml Fentanyl B. Braun 0.5 mg contains 500 micrograms of fentanyl, as fentanyl citrate, 785 micrograms.

Excipient with known effect: Sodium 3.54 mg/ml

Excipients: Sodium chloride, water for injections.

## **THERAPEUTIC INDICATIONS**

Fentanyl B. Braun is a short acting opioid used for neuroleptanalgesia and neuroleptanaesthesia; as an analgesic component in general anaesthesia with intubation and ventilation of the patient; for analgesic treatment of artificially ventilated patients in intensive care.

## **CONTRAINDICATIONS**

Hypersensitivity to fentanyl or other opioids or to any of the excipients listed.

## **UNDESIRABLE EFFECTS**

Most of the undesirable effects that have been observed during or after the administration of fentanyl are closely related to its pharmacological effects. So, except for the hypersensitivity reactions stated below, both frequency and severity of the undesirable effects are dose-dependent. The frequencies stated below refer to the normal clinical dose range. In particular, the following effects have been observed:

Undesirable effects are listed according to their frequencies as follows:

Very common: ( $\geq 1/10$ )

Common: ( $\geq 1/100$  to  $< 1/10$ )  
Uncommon: ( $\geq 1/1\ 000$  to  $< 1/100$ )  
Rare: ( $\geq 1/10\ 000$  to  $< 1/1000$ )  
Very rare: ( $< 1/10\ 000$ )  
Not known: (cannot be estimated from the available data)

### ***Immune system disorders***

Common: Hypersensitivity reactions manifesting as sweating, pruritus and urticaria

### ***Endocrine disorders***

Very common: Antidiuretic hormone release

### ***Psychiatric disorders***

Common: Agitation  
Uncommon: Euphoric mood  
Not known: Delirium

### ***Nervous system disorders***

Very common: Drowsiness, sedation, vertigo, increased intracranial pressure  
Common: Confusion, CNS depression  
Rare: Convulsions  
Not known: Myoclonus, serotonin syndrome

Administration of fentanyl over a longer period of time may cause the development of tolerance. The development of drug dependence cannot be ruled out.

### ***Eye disorders***

Very common: Miosis  
Common: Disturbances of vision

### ***Cardiac disorders***

Common: Cardiac arrhythmias, tachycardia, bradycardia  
Rare: Severe bradycardia, up to cardiac arrest  
Bradycardia can be treated by administration of atropine.

### ***Vascular disorders***

Very common: Peripheral vasodilation  
Common: Hypotension, hypertension, orthostatic hypotension

### ***Respiratory, thoracic and mediastinal disorders***

Very common: Coughing at induction of anaesthesia (dose-dependent)  
Common: Transient apnoea, postoperative respiratory depression

Rare: Hypercapnia, laryngospasm, severe respiratory depression up to respiratory arrest (after high doses). The respiratory depressant effect may last longer than the analgesic effect and may re-appear in the postoperative period. Postoperative monitoring is therefore mandatory

Very rare: Bronchospasm, pulmonary oedema

Airway conductance may be impaired by glottis closure through glottis rigidity.

### ***Gastrointestinal disorders***

Very common: Nausea, vomiting

Common: Constipation due to the opioid specific effect of fentanyl on smooth muscles

Not known: Ileus

### ***Musculoskeletal and connective tissue disorders***

Very common: After high i.v. doses an increased tension of skeletal muscles (muscle rigidity), especially thoracic stiffness resulting in impaired ventilation can occur. This may require application of muscle relaxants.

### ***Renal and urinary disorders***

Common: Urine retention

### ***General disorders and administration site conditions***

Not known: Habituation, drug withdrawal syndrome

### ***Injury, poisoning and procedural complications***

Uncommon: Post-operative confusion

### **Paediatric population**

After infusions of fentanyl in children over prolonged periods, movement disturbances, increased sensitiveness and opioid withdrawal symptoms have been observed.

## **WARNINGS**

Keep out of the sight and reach of children.

Only to be used if solution is clear, colourless and container undamaged.

## **NOTE**

*Prescription only, narcotic*

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.

**B. Braun Melsungen AG, 34212 Melsungen, Germany, 08/2023**