NAME OF THE MEDICINAL PRODUCT

Remifentanil B. Braun 1 mg, powder for concentrate for solution for injection or infusion.
Remifentanil B. Braun 2 mg, powder for concentrate for solution for injection or infusion.
Remifentanil B. Braun 5 mg, powder for concentrate for solution for injection or infusion.

COMPOSITION

One vial contains remifentanil hydrochloride equivalent to 1 mg remifentanil.
One vial contains remifentanil hydrochloride equivalent to 2 mg remifentanil.
One vial contains remifentanil hydrochloride equivalent to 5 mg remifentanil.

Each ml of Remifentanil B. Braun 1 mg/ 2 mg/ 5 mg, powder for concentrate for solution for injection or infusion contains 1 mg remifentanil when reconstituted as directed.

Excipients: Glycine, hydrochloric acid (for pH-adjustment).

THERAPEUTIC INDICATIONS

Remifentanil is indicated as an analgesic agent for use during induction and/or maintenance of general anaesthesia.
Remifentanil is indicated for provision of analgesia in mechanically ventilated intensive care patients 18 years of age and over.

CONTRAINDICATIONS

As glycine is present in the formulation, Remifentanil B. Braun is contraindicated for epidural and intrathecal use.
Remifentanil B. Braun is contraindicated in patients with known hypersensitivity to remifentanil and other fentanyl analogues or any other component of the preparation.
Remifentanil is contra-indicated for use as the sole agent for induction of anaesthesia.

UNDESIRABLE EFFECTS

The most common undesirable effects associated with remifentanil are direct extensions of μ-opioid agonist activities. These adverse events resolve within minutes of discontinuing or decreasing the rate of remifentanil administration.

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)
Not known: (cannot be estimated from the available data)

System organ class

Immune system disorders
Rare: Hypersensitivity reactions including anaphylaxis have been reported in patients receiving remifentanil in conjunction with one or more anaesthetic agents

Psychiatric disorders
Not known: Drug dependence, withdrawal syndrome

Nervous system disorders
Very common: Skeletal muscle rigidity
Rare: Sedation (during awakening after general anaesthesia)
Not known: Convulsions

Cardiac disorders
Common: Bradycardia
Rare: Asystole/cardiac arrest with preceding bradycardia in patients treated with remifentanil in combination with other anaesthetics
Not known: Atrioventricular block, arrhythmia

Vascular disorders
Very common: Hypotension
Common: Post-operatively occurring hypertension

Respiratory, thoracic and mediastinal disorders
Common: Acute respiratory depression, apnoea, cough
Uncommon: Hypoxia

Gastrointestinal disorders
Very common: Nausea, vomiting

Uncommon: Constipation

Skin and subcutaneous tissue disorders
Common: Pruritus

General disorders and administration site conditions
Common: Post-operative shivering
Uncommon: Post-operative pain
Not known: Drug tolerance

Discontinuation of treatment
Symptoms following withdrawal of remifentanil including tachycardia, hypertension and agitation have been reported infrequently upon abrupt cessation, particularly after prolonged administration of more than 3 days.

WARNING

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.

B. Braun Melsungen AG, 34212 Melsungen, Germany, 05/2022