## NAME OF THE MEDICINAL PRODUCT

Naloxone HCl 0.4 mg/ml solution for injection/infusion

## COMPOSITION

Each ampoule of 1 ml contains 0.4 mg naloxone hydrochloride (as naloxone hydrochloride dihydrate).

*Excipients:*
1 ml solution for injection/infusion contains 3.54 mg of sodium.
Water for injections, sodium chloride, hydrochloric acid, diluted (for pH adjustment).

## THERAPEUTIC INDICATIONS

Complete or partial reversal of CNS and especially respiratory depression, caused by natural or synthetic opioids. Diagnosis of suspected acute opioid overdose or intoxication. Complete or partial reversal of respiratory and other CNS depression in the neonate whose mothers have received opioids.

## CONTRAINDICATIONS

Naloxone HCl 0.4 mg/ml is contraindicated in patients with hypersensitivity to naloxone hydrochloride or to any of the excipients of this medicinal product.

## 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)

***System organ class***

***Immune systems disorders***
Very rare: Allergic reactions (urticaria, rhinitis, dyspnoea, Quincke's oedema), anaphylactic shock

***Nervous system disorders***
Common: Dizziness, headache
Uncommon: Tremor, sweating
Rare: Seizures, tension

Seizures have occurred rarely following administration of naloxone hydrochloride; however, a causal relationship to the drug has not been established. Higher than recommended dosage in postoperative use can lead to tension.

***Cardiac disorders***
Common: Tachycardia
Uncommon: Arrhythmia, bradycardia
Very rare: Fibrillation, cardiac arrest

***Vascular disorders***
Common: Hypotension, hypertension

Hypotension, hypertension and cardiac arrhythmia (including ventricular tachycardia and fibrillation) have also occurred with the postoperative use of naloxone hydrochloride. Adverse cardiovascular effects have occurred most frequently in postoperative patients with a pre-existing cardiovascular disease or in those receiving other drugs that produce similar adverse cardiovascular effects.

***Respiratory, thoracic and mediastinal disorders***
Very rare: Pulmonary oedema

Pulmonary oedema has also occurred with the postoperative use of naloxone hydrochloride.

***Gastrointestinal disorders***
Very common: Nausea
Common: Vomiting
Uncommon: Diarrhoea, dry mouth

Nausea and vomiting have been reported in postoperative patients who have received doses higher than recommended. However, a causal relationship has not been established, and the symptoms may be signs of too rapid antagonisation of the opioid effect.

***Skin and subcutaneous tissue disorders***
Very rare: Erythema multiforme

One case of erythema multiforme cleared promptly after naloxone hydrochloride was discontinued.

***General disorders and administration site conditions***
Common: Postoperative pain
Uncommon: Hyperventilation, irritation of vessel wall (after i.v. administration); local irritation and inflammation (after i.m. administration)

Higher than recommended dosage in postoperative use can lead to the return of pain. A fast reversal of opioid effect can induce hyperventilation.

## WARNINGS

Keep out of 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, 34209 Melsungen, Germany, 12/2017**

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**Document Control**
**& Signature Page**

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