NAME OF THE MEDICINAL PRODUCT

Rocuronium B. Braun 10 mg/ml solution for injection/infusion

COMPOSITION

The solution for injection/infusion contains:

1 ml of solution for injection/infusion contains 10 mg rocuronium bromide.
Each ampoule with 5 ml contains 50 mg rocuronium bromide.

Excipients:
Gluconolactone Sodium acetate trihydrate, sodium citrate dihydrate, water for injections.

THERAPEUTIC INDICATIONS

Rocuronium bromide is indicated in adults and paediatric patients (from term neonates to adolescents, 0 to < 18 years) as an adjunct to general anaesthesia to facilitate tracheal intubation during routine sequence induction and to provide skeletal muscle relaxation during surgery.
In adults, rocuronium bromide is also indicated to facilitate tracheal intubation during rapid sequence induction and as an adjunct in the intensive care unit (ICU) to facilitate intubation and mechanical ventilation, for short term use.

CONTRAINDICATIONS

Rocuronium bromide is contra-indicated in patients with hypersensitivity to rocuronium or to the bromide ion or to any of the excipients.

UNDESIRABLE EFFECTS

Undesirable effects are listed according to their frequencies as follows:

Uncommon/rare:	(≥ 1/10 000 to < 1/100)
Very rare:	(< 1/10 000)
Not known:	(frequency cannot be estimated from the available data)

Frequencies are estimates derived from post-marketing surveillance reports and data from the general literature.

Post-marketing surveillance data cannot give precise incidence figures. For that reason, the reporting frequency was divided over three rather than five categories.

The most common undesirable effects are pain and/or local reactions around injection site, changes in vital functions and prolonged neuromuscular block. The most frequently reported serious adverse drug reactions during post-marketing surveillance is 'anaphylactic and anaphylactoid reactions' and associated symptoms. See also the explanations below.

System organ class

Immune system disorders
Very rare: Hypersensitivity, anaphylactic reaction *, anaphylactoid reaction*, anaphylactic shock, anaphylactoid shock

Nervous system disorders
Very rare: Flaccid paralysis

Cardiac disorders
Uncommon/rare: Tachycardia
Not known*:* Kounis syndrome

Vascular disorders
Uncommon/rare: Hypotension
Very rare: Circulatory collapse and shock, flushing

Respiratory, thoracic and mediastinal disorders
Very rare: Bronchospasm
Not known: Apnoea*,* respiratory failure

Skin and subcutaneous tissue disorders
Very rare: Rash, erythematous rash, angioneurotic oedema, urticaria, itching, exanthema

Musculoskeletal,connective tissue and bone disorders
Very rare: Skeletal muscle weakness (after long-term use in the ICU), steroid myopathy (after long-term use in the ICU)

General disorders and administration site conditions
Very rare: Face oedema
Uncommon/rare: Drug ineffective, drug effect/ therapeutic response decreased, drug effect/ therapeutic response increased**,** injection site pain and/or local reactions*

Investigations
Very rare: Increased histamine level*

Injury, poisoning and procedural complications
Very rare: Airway complication of anaesthesia
Uncommon/rare: Prolonged neuromuscular block*, delayed recovery from anaesthesia

Paediatric population:
A meta-analysis of 11 clinical studies in paediatric patients (n=704) with rocuronium bromide (up to 1 mg/kg) showed that tachycardia was identified as adverse drug reaction with a frequency of 1.4%.

***Information on particular undesirable effects**
Anaphylaxis
Although very rare, severe anaphylactic/anaphylactoid reactions to neuromuscular blocking agents including rocuronium bromide have been reported. Anaphylactic/anaphylactoid reactions are: bronchospasm, cardiovascular changes (e.g. hypotension, tachycardia, circulatory collapse – shock), and cutaneous changes (e.g. angioedema, urticaria). These reactions have, in some cases been fatal. Due to the possible severity of these reactions, one should always assume they may occur and take the necessary precautions.

Local injection site reactions
During rapid sequence induction of anaesthesia, pain on injection has been reported, especially when the patient has not yet completely lost consciousness and particularly when propofol is used as the induction agent. In clinical studies, pain on injection has been noted in 16% of the patients who underwent rapid sequence induction of anaesthesia with propofol and in less than 0.5% of the patients who underwent rapid sequence induction of anaesthesia with fentanyl and thiopental.

Increased histamine level
Since neuromuscular blocking agents are known to be capable of inducing histamine release both locally at the site of injection and systemically, the possible occurrence of itching and erythematous reaction at the site of injection and/or generalised histaminoid (anaphylactoid) reactions (see also under anaphylactic reactions above) should always be taken into consideration when administering these drugs.

In clinical studies only a slight increase in mean plasma histamine level has been observed following rapid bolus administration of 0.3 - 0.9 mg rocuronium bromide per kg body weight.

Prolonged neuromuscular block
The most frequent adverse reaction to non-depolarising blocking agents as a class consists of an extension of the agent's pharmacological action beyond the time period needed. This may vary from skeletal muscle weakness to profound and prolonged skeletal muscle paralysis resulting in respiratory insufficiency or apnoea.

Myopathy
Myopathy has been reported after the use of various neuromuscular blocking agents in the ICU in combination with corticosteroids.

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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