NAME OF THE MEDICINAL PRODUCT

Paracetamol B. Braun 10 mg/ml solution for infusion

COMPOSITION

The solution for infusion contains:

1 ml	10 mg paracetamol
In 1 ampoule of 10 ml	100 mg paracetamol
In 1 bottle of 50 ml	500 mg paracetamol
In 1 bottle of 100 ml	1 000 mg paracetamol

Excipients:
Mannitol, sodium citrate dihydrate, acetic acid glacial (for pH adjustment), water for injections.

THERAPEUTIC INDICATIONS

Paracetamol B. Braun is indicated for:

- Short-term treatment of moderate pain, especially following surgery
- Short-term treatment of fever

When administration by intravenous route is clinically justified by an urgent need to treat pain or hyperthermia and/or when other routes of administration are not possible.

CONTRAINDICATIONS

Hypersensitivity to paracetamol, propacetamol hydrochloride (prodrug of paracetamol) or to any of the excipients. Cases of severe hepatocellular insufficiency.

UNDESIRABLE EFFECTS

Undesirable effects are listed according to their frequencies as follows:

Rare: (≥ 1/10 000 to < 1/1 000)
Very rare: (<1/10 000)

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

System Organ Class	**Rare** (≥1/10 000 to <1/1 000)	**Very rare** (<1/10 000)	**Not known** (cannot be estimated from the available data)
Blood and lymphatic system disorders	-	Thrombocytopenia, Leucopenia, Neutropenia	-
Immune system disorders	-	Hypersensitivity reaction (1, 3)	-
Cardiac disorders	-	-	Tachycardia (2)
Vascular disorders	Hypotension	-	Flushing (2)
Hepatobiliary disorders	Increased levels of hepatic transaminases	-	-
Skin and subcutaneous tissue disorders	-	Serious skin reactions (3)	Pruritus (2), Erythema (2)
General disorders and administration site conditions	Malaise	-	-

(1) Very rare cases of hypersensitivity reactions ranging from simple skin rash or urticaria to anaphylactic shock have been reported and require discontinuation of treatment.
(2) Isolated cases.
(3) Very rare cases of serious skin reactions have been reported.

Frequent adverse reactions at injection site have been reported during clinical trials (pain and burning sensation).

WARNINGS

Keep out of the sight and reach of children.
The maximum daily dose should be adjusted for patients receiving other paracetamol containing products.

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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