

NAME OF THE MEDICINAL PRODUCT

Granisetron B. Braun 1 mg/ml concentrate for solution for injection or infusion

COMPOSITION

1 ml concentrate for solution for injection or infusion contains 1 mg granisetron (as the hydrochloride).

Excipients:

Up to 4.5 mg of sodium per 1 ml solution.

Sodium chloride, citric acid monohydrate, sodium hydroxide (for pH adjustment), water for injection.

THERAPEUTIC INDICATIONS

Adults

Prevention and treatment of acute nausea and vomiting associated with chemotherapy and radiotherapy. Prevention and treatment of post-operative nausea and vomiting.

Granisetron B. Braun is indicated for the prevention of delayed nausea and vomiting associated with chemotherapy and radiotherapy.

Paediatric population

Granisetron B. Braun is indicated in children aged 2 years and above for the prevention and treatment of acute nausea and vomiting associated with chemotherapy.

CONTRAINDICATIONS

Hypersensitivity to the active substance or any of the excipients.

UNDESIRABLE EFFECTS

The most frequently reported adverse reactions for granisetron are headache and constipation which may be transient. ECG changes including QT prolongation have been reported.

The following adverse reactions are derived from clinical trials and post-marketing data associated with granisetron and other 5-HT₃ antagonists.

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 $< 1/100$)

System organ class

Immune system disorders

Uncommon: Hypersensitivity reactions e.g. anaphylaxis, urticaria

Psychiatric disorders

Common: Insomnia

Nervous system disorders

Very common: Headache

Uncommon: Extrapyrimal Reactions, serotonin syndrome

Cardiac disorders

Uncommon: QT prolongation

Gastrointestinal disorders

Very common: Constipation

Common: Diarrhoea

Hepatobiliary disorders

Common: Elevated hepatic transaminases. Occurred at a similar frequency in patients receiving comparator therapy

Skin and subcutaneous tissue disorders

Uncommon: Rash

Description of selected adverse reactions

As for other 5-HT₃ antagonists, ECG changes including QT prolongation have been reported with granisetron.

WARNINGS

Keep out of the sight and reach of children. For single use only.

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, 01/2017

Title: Granisetron Initiator: Inge ? Pohlmann

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