FRESENIUS KABI

NAPPI code

720942001 | Pack size: 5

GRANISETRON 1 mg/mL (1 mL) FRESENIUS

Concentrate for solution for injection/infusion

NAPPI code

720943001 | Pack size: 5

GRANISETRON 1 mg/mL (3 mL) FRESENIUS

Concentrate for solution for injection/infusion

Indications

- For the prevention and treatment of nausea and vomiting induced by cytostatic therapy (chemotherapy and radiotherapy)
- For the prevention and treatment of post-operative nausea and vomiting

Shelf life

Unopened: 3 years

After opening: The product must be used immediately after first opening.

After dilution: The product should be used immediately.

Special precautions for storage

Store at or below 25 °C. Do not freeze.

Keep the ampoules in the outer carton to protect from light.

Posology and method of administration

Posology
Chemotherapy induced nausea and vomiting (CINV)
Adults:
Intravenous:
Prevention: A dose of 1 – 3 mg (10 – 40 µg/kg) of GRANISETRON FRESENIUS should be administered either as a slow intravenous injection (over 30 seconds) or as an intravenous infusion diluted in 20 to 50 mL infusion fluid and administered over 5 minutes, prior to the start of chemotherapy.
Treatment: A dose of 1 – 3 mg (10 – 40 µg/kg) of GRANISETRON FRESENIUS should be administered either as a slow intravenous injection (over 30 seconds) or as an intravenous infusion diluted in 20 to 50 mL infusion fluid and administered over 5 minutes. Further treatment doses of GRANISETRON FRESENIUS may be administered, if required, at least 10 minutes apart. The maximum dose of GRANISETRON FRESENIUS to be administered over 24 hours should not exceed 9 mg.
Intramuscular:
Prevention and treatment:
A dose of 3 mg of GRANISETRON FRESENIUS should be administered by the intramuscular route, 15 minutes prior to the start of chemotherapy. Two subsequent 3 mg doses of GRANISETRON FRESENIUS may be administered, if required, within a 24 hour period.
Paediatrics (children of 2 years and older):
Intravenous:
A dose of 10 – 40 µg/kg body weight (up to 3 mg) should be administered as an intravenous infusion, diluted in 10 to 30 mL infusion fluid and administered over 5 minutes prior to the start of chemotherapy. One additional dose may be administered within a 24 hour period if required. This additional dose should not be administered until at least 10 minutes after the initial infusion.
Intramuscular:
Insufficient data are currently available to recommend the use of GRANISETRON FRESENIUS by the intramuscular route in children.

Radiotherapy induced nausea and vomiting (RINV)
Adults:
Intravenous:
Prevention: A dose of 1 – 3 mg (10 – 40 µg/kg) of GRANISETRON FRESENIUS should be administered either as a slow intravenous injection (over 30 seconds) or as an intravenous infusion diluted in 20 to 50 mL infusion fluid and administered over 5 minutes, prior to the start of radiotherapy.
Paediatrics:
There is insufficient information to recommend the use of GRANISETRON FRESENIUS in the prevention and treatment of RINV in children.

Post operative nausea and vomiting (PONV)
Adults:
Intravenous:
Prevention: A dose of 1 mg (10 µg/kg) of GRANISETRON FRESENIUS should be administered as a slow intravenous injection (over 30 seconds) prior to induction of anaesthesia.
Treatment: A dose of 1 mg (10 µg/kg) of GRANISETRON FRESENIUS should be administered by slow intravenous injection (over 30 seconds). The maximum dose for patients undergoing anaesthesia for surgery is a total dose of 3 mg GRANISETRON FRESENIUS intravenous in one day.
Paediatrics:
There is insufficient information to recommend the use of GRANISETRON FRESENIUS in the prevention and treatment of PONV in children.

Elderly: No dosage adjustment required.
Renal impairment: No dosage adjustment required.
Hepatic impairment: No dosage adjustment required.

Method of administration
Intravenous infusion, slow intravenous injection or intramuscular injection.
Prophylactic administration of GRANISETRON FRESENIUS should be completed prior to the start of cytostatic therapy or induction of anaesthesia.

S4 GRANISETRON 1 mg/mL (1 mL) FRESENIUS. Each 1 mL ampoule contains granisetron hydrochloride equivalent to 1 mg granisetron.
Reg No.: 44/5.7.2/0671

S4 GRANISETRON 1 mg/mL (3 mL) FRESENIUS. Each 3 mL ampoule contains granisetron hydrochloride equivalent to 3 mg granisetron.
Reg No.: 44/5.7.2/0672

For full prescribing information refer to the latest professional information approved by the South African Health Products Regulatory Authority.

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FRESENIUS KABI

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