HOSPITALS

PACKAGE LEAFLET:
INFORMATION FOR THE USER

GRANISETRON TEVA 1 mg/1 ml CONCENTRATE FOR SOLUTION FOR INFUSION OR INJECTION

Granisetron

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse or pharmacist.
- This medicine has been prescribed to you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse or pharmacist.

In this leaflet:

1 WHAT GRANISETRON TEVA IS AND WHAT IT IS USED FOR

Granisetron Teva contains a medicine called granisetron. This belongs to a group of medicines called '5-HT_3 receptor antagonists' or 'anti-emetics'.

Granisetron Teva is used to prevent or treat nausea and vomiting (feeling and being sick) caused by other medical treatments, such as chemotherapy or radiotherapy for cancer, and by surgery.

The solution for injection is for use in adults and children from 2 years old.

2 BEFORE YOU ARE GIVEN GRANISETRON TEVA

Do NOT use Granisetron Teva:
- If you are allergic (hypersensitive) to granisetron or any of the other ingredients of Granisetron Teva (listed in Section 6: Further information).

If you are not sure, talk to your doctor, nurse or pharmacist before having the injection.

Take special care with Granisetron Teva:
Check with your doctor, nurse or pharmacist before using granisetron if you:
- are having problems with your bowel movements because of a blockage of your gut (intestines)
- have heart problems, are being treated for cancer with a medicine that is known to damage your heart or have problems with levels of salts, such as potassium, sodium or calcium, in your body (electrolyte abnormalities)
- are taking other '5-HT_3 receptor antagonist' medicines. These include dolasetron, ondansetron used like granisetron in the treatment and prevention of nausea and vomiting.

Taking other medicines
Please tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is because Granisetron Teva can affect the way some medicines work. Also some other medicines can affect the way this injection works.

In particular, tell your doctor, nurse or pharmacist if you are taking the following medicines:
- medicines used to treat an irregular heartbeat other '5-HT_3 receptor antagonist' medicines such as dolasetron or ondansetron (see "Take special care with Granisetron Teva" above)
- phenobarbital, a medicine used to treat epilepsy
- a medicine called ketoconazole used in the treatment of fungal infections
- the antibiotic erythromycin used to treat bacterial infections.

Pregnancy and breast-feeding
You should not have this injection if you are pregnant, trying to get pregnant or are breast-feeding, unless your doctor has told you to.

Ask your doctor, nurse or pharmacist for advice before taking any medicine.

Driving and using machines
Granisetron Teva is not likely to affect your ability to drive or use any tools or machines.

Important information about some of the ingredients of Granisetron Teva
This medicinal product contains 0.15 mmol (3.5 mg) **sodium** per ml. To be taken into consideration by patients on a controlled sodium diet, if the dose exceeds 6.6 ml.

3 HOW GRANISETRON TEVA WILL BE GIVEN

The injection will be given to you by a doctor or nurse. The dose of Granisetron Teva varies from one patient to another. It depends on your age, weight, and whether you are being given the medicine to prevent, or treat, nausea and vomiting. The doctor will work out how much to give you.

Granisetron can be given as an injection into the veins (intravenous).

Prevention of feeling or being sick following radio- or chemotherapy
You will be given the injection before your radio- or chemotherapy starts. The injection into your veins will take between 30 seconds and 5 minutes and the dose will usually be between 1 and 3 mg. The medicine may be diluted before it is injected.

Treatment of feeling or being sick following radio- or chemotherapy
The injection will take between 30 seconds and 5 minutes and the dose will usually be between 1 and 3 mg. The medicine may be diluted before it is injected into your veins. You may be given more injections to stop your sickness after the first dose. There will be at least 10 minutes between each injection. The most Granisetron Teva you will be given is 9 mg in a day.

Combination with steroids
The effect of the injection may be improved by the use of medicines called adrenocortical steroids. The steroid will be given either as a dose between 8 and 20 mg dexamethasone before your radio- or chemotherapy or as a 250 mg methyl-prednisolone, which will be given both before and after your radio-or chemotherapy.

Use in children in the prevention or treatment of feeling or being sick following radio- or chemotherapy
Children will be given granisetron by injections into the vein as described above with the dose depending on the child's weight. The injections will be diluted and be given before radio- or chemotherapy and will take 5 minutes. Children will be given a maximum of 2 doses a day, at least 10 minutes apart.

Treatment of feeling or being sick following surgery
The injection into your veins will take between 30 seconds and 5 minutes and the dose will usually be 1 mg. The most granisetron you will be given is 3 mg a day.

Use in children in the prevention or treatment of feeling or being sick following surgery
Children should not be given this injection to treat sickness or the feeling of sickness after surgery.

If you are given too much Granisetron Teva
Because the injection will be given to you by a doctor or nurse, it is unlikely that you will be given too much. However, if you are worried talk to your doctor or nurse. Symptoms of overdose include mild headaches. You will be treated depending on your symptoms.

If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

4 POSSIBLE SIDE EFFECTS

Like all medicines, Granisetron Teva can cause side effects, although not everybody gets them. If you notice the following you must see a doctor straight away.
- allergic reactions (anaphylaxis). The signs may include swelling of the throat, face, lips and mouth, difficulty in breathing or swallowing.

Other side effects that may be experienced while taking this medicine are:

Very common: affects more than 1 user in 10
- headache
- constipation. Your doctor will monitor your condition.

Common: affects 1 to 10 users in 100
- problems sleeping (insomnia)
- changes in how your liver is working shown by blood tests
- diarrhoea.

Uncommon: affects up to 1 to 10 users in 1,000
- skin rashes or an allergic skin reaction or "nettle-rash" or "hives" (urticaria). The signs may include red, raised itchy bumps
- changes in the heartbeat (rhythm) and changes seen on ECG readings (electrical recordings of the heart)
- abnormal involuntary movements, such as shaking, muscle rigidity and muscle contractions.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

5 HOW TO STORE GRANISETRON TEVA

Keep out of the reach and sight of children.

Do not use after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of the month.

Do not freeze. Keep the container in the outer carton in order to protect from light.

Do not use this product if you notice that the solution is brown.

The product should be used immediately after opening and dilution.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 FURTHER INFORMATION

What Granisetron Teva contains:
- The active ingredient is granisetron. One ml of concentrate for solution for infusion or injection contains 1 mg granisetron (as hydrochloride). Each ampoule or vial contains 1 mg granisetron (as hydrochloride).
- The other ingredients are sodium chloride, sodium hydroxide, hydrochloric acid and water for injections.

What Granisetron Teva looks like and contents of the pack:
- Concentrate for solution for infusion or injection
- Sterile, clear, colourless solution
- 1 ml in clear glass type I ampoules Pack sizes: 1, 5 or 10 ampoules.
- 1 ml in clear glass type I vials, sealed with rubber stopper and green cap
  Pack sizes: 1, 5 or 10 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Teva Pharma B.V.
Computerweg 10
3542 DR Utrecht
The Netherlands

Manufacturer
1. TEVA UK Ltd, Brampton Road, Hampden Park, Eastbourne, East Sussex, BN22 9AG, England.
2. Pharmachemie B.V., Swensweg 5, Postbus 552, 2003 RN Haarlem, The Netherlands.
3. TEVA Santé SA, Rue Bellocier, 89107 Sens, France.
4. TEVA Pharmaceutical Works Private Limited Company, Táncsics Mihály út 82, H-2100 Gödöllő, Hungary.

This leaflet was last revised in 02/2012.

The following information is intended for medical or healthcare professionals only:

Incompatibilities
As a general safety rule, Granisetron Teva should never be mixed in solution with other drugs. Prophylactic infusion of Granisetron Teva should be completed before the start of cytostatic therapy.

Preparation and administration of Granisetron Teva solution for infusion or injection

Prevention and treatment of post-operative nausea and vomiting:

Adults:
A 1 mg dose is prepared by withdrawing 1 ml from the ampoule and diluting it to 5 ml with 0.9% w/v sodium chloride solution. No other solutions should be used.

The dose should be administered as a slow intravenous injection given over 30 seconds.

Children:
There is no experience in the use of granisetron in the prevention and treatment of post-operative nausea and vomiting in children, therefore it is not recommended for this indication in this age group.

Children and teenagers aged 2 to 16 years:
A 40 µg/kg dose is prepared by withdrawing the appropriate amount and diluting with infusion fluid to a total volume between 10 and 30 ml. Any of the following solutions may be used:
- 0.9% w/v sodium chloride solution
- 0.18% w/v sodium chloride and 4% w/v glucose solution
- 5% w/v glucose solution
- Hartmann's solution for injection
- Sodium lactate solution
- 10% mannitol solution

No other solutions should be used.

The dose should be administered as an intravenous infusion given over 5 minutes.

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Design Department Harlow

PRODUCT: Granisetron Teva 1 mg/1 ml Sol in Vials ALL TEI (V2)	**Colours:** Cutter Guide, Black	**Fonts: (Artwork)** Body: Syntax ALL 8.5 pts Subhead: Univers 65 Bld 8.5 pts Header: Univers 65 Bld 10 pts	**Amends:** Draft: 4 Rev date: 14-1-13 Reviser: YA	**Approval:** Senior Artwork Co-ordinator
Job No: 21197 Art No: x				Signed / Date
Designer: gc Date: 5-10-11	Tints used:			• Subject to Reg. Agency approval • Approved by Reg. Dept. for print
Component: Leaflet		Software used: Indesign CS5	Artworker's Signature:	Signed / Date
Dimensions: 120x360 mm	Spellcheck:			

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Last amend: