

Granisetron 1 mg/ml

concentrate for solution for injection or infusion

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 pharmacist.
- This medicine has been prescribed for 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 become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Granisetron hydrochloride

In this leaflet:

1. What Granisetron is and what it is used for
2. Before you use Granisetron
3. How to use Granisetron
4. Possible side effects
5. How to store Granisetron
6. Further information

1. WHAT GRANISETRON IS AND WHAT IT IS USED FOR

Granisetron belongs to a group of medicines called 5-HT₃ receptor antagonists which act as anti-emetics.

It is used to prevent and treat the nausea (feeling sick) and vomiting (being sick) that may occur after treatment with anticancer medicines (chemotherapy) or with radiation therapy.

Granisetron may be administered to adults, adolescents and children of at least two years of age.

2. BEFORE YOU USE GRANISETRON

Do not use Granisetron

- if you are **allergic** (hypersensitive) to granisetron, to any of the other ingredients in Granisetron or to any medicinal products acting like Granisetron (like other 5-HT₃ receptor antagonists, such as ondansetron)
- in **children under 2 years** of age, because insufficient experience is available.

Take special care with Granisetron

- if you have been told by a doctor that your **bowels** don't work properly
- if you have any **pain in your abdomen** (tummy) or your abdomen feels distended or swollen after having taken Granisetron
- if you have **severe constipation**.
- if you are on a **low sodium diet** (one ml of the drug contains up to 4.5 mg of sodium)
- if you have heart rhythm disorders

Please note:

Children

This medicine has been tested in children 2 years of age and older who were treated with anticancer medicines. In effective doses it has not been shown to cause different side effects or problems than it does in adults.

Elderly

This medicine has been tested in a limited number of patients 65 years of age or older and has not been shown to cause any other side effects or problems in older people than it does in younger adults.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Using Granisetron with food and drink

You don't have to pay any special attention concerning food and drink.

Pregnancy and breast-feeding

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

Granisetron has not been studied in pregnant women. However, Granisetron has not been shown to cause any birth defects or other problems in animal studies. Before taking this medicine, make sure your doctor knows if you are pregnant or if you may become pregnant. This drug should be used during pregnancy only if clearly needed and after your doctor has weighed up risks and benefits.

It is not known whether granisetron passes into the breast milk of nursing mothers. If you are breast-feeding while you are treated with Granisetron you should discuss this with your doctor.

Driving and using machines

After being treated with Granisetron there is a chance that you may feel drowsy or sleepy. Depending on your individual reaction this may compromise your ability to drive, to operate machinery or to work at high altitude. If that happens you should not drive by yourself, not operate machinery and not carry out any work that requires a safe foothold until you're aware of how this drug affects you.

Important information about some of the ingredients of Granisetron

1 ml of Granisetron contains up to 4.5 mg of sodium. **If you are on a controlled sodium diet, please contact your doctor immediately.**

3. HOW TO USE GRANISETRON

Dosage

The usual doses are:

Prevention and treatment of nausea and vomiting after cancer chemotherapy or radiation therapy

In adults The recommended dose is 1 mg or 3 mg depending on the kind of chemotherapy or radiotherapy. To stop any sickness that may occur after the treatment, the same dose may be given to you up to twice more within 24 hours if needed.

No more than 9 mg should be given to you in one day.

In children The dose is based on the body weight and must be determined by the doctor: 0.02-0.04 mg for each kilogram (kg) of body weight (up to 3 mg) to prevent sickness before anticancer treatment. An additional dose of 40 microgram/kg (up to 3 mg) may be administered within a 24 hour period either as a single dose or as two divided doses.

Method and route of administration

Usually Granisetron will be given to you by your doctor or nurse, before or during the treatment that is likely to make you feel sick. It can also be given afterwards to stop any sickness you may be having.

In adults Granisetron can be given diluted as an intravenous injection (into a vein) over 30 seconds or as an intravenous infusion (over a longer time).

In children Granisetron can be given as an intravenous infusion diluted in infusion fluid over five minutes.



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

PREPARATION GUIDE FOR:

Granisetron 1 mg/ml concentrate for solution for injection or infusion

It is important that you read the entire contents of this guide prior to the preparation of this medicinal product.

PRESENTATION

Granisetron is supplied as a concentrate for solution for intravenous injection or infusion in colourless glass ampoules with a volume of 1 ml or 3 ml containing a sterile, clear colourless solution.

PREPARATION FOR THE INTRAVENOUS ADMINISTRATION

In adults, Granisetron can be administered as an

intravenous bolus over not less than 30 seconds diluted with infusion fluid. The contents of a 1 ml ampoule can be diluted to a volume of 5 ml; the contents of a 3 ml ampoule can be diluted to a volume of 15 ml.

Granisetron can also be diluted in 20 to 50 ml of infusion fluid and then given over 5 minutes as an intravenous infusion.

In children, Granisetron should be diluted to a total volume of 10 ml to 30 ml and administered by intravenous infusion over 5 minutes.

Granisetron is compatible with the following solutions: 0.9% w/v sodium chloride injection

If you use more Granisetron than you should or if you forget to use Granisetron

Since Granisetron will be administered to you by a doctor or nurse, it is unlikely that you will be given too much or that you will miss a dose.

Further questions

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

For information intended for medical or healthcare professionals please see the appropriate section below.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Granisetron can cause side effects, although not everybody gets them. The most frequent side effects of Granisetron are headache and constipation.

Serious side effects

You should tell your doctor immediately if you become **short of breath** or get a **swollen face**. These reactions are rare but need urgent medical treatment.

Tell your doctor if you get a rash or start to itch.

Other side effects

Very common side effects (probably affecting more than 1 in 10 people):

- Headache

Common side effects (probably affecting fewer than 1 in 10 people):

- High blood pressure (hypertension)
- Feeling anxious (anxiety)
- Restlessness (agitation)
- Sleeplessness (insomnia), sleepiness (somnolence)
- Dizziness
- Weakness (asthenia)
- Diarrhoea
- Constipation
- Loss of appetite (anorexia)
- Taste disorder
- Fever

Uncommon side effects (probably affecting fewer than 1 in 100 people):

- Disturbances of vision
- Skin rashes

Rare side effects (probably affecting fewer than 1 in 1,000 people):

- Irregular rhythm of the heartbeat (arrhythmias: sinus bradycardia, atrial fibrillation, varying degrees of AV-block, ventricular ectopy)
- Abnormalities in the ECG (prolonged ECG intervals)
- Muscle coordination problems like twisting, repetitive movements or abnormal postures (Dystonia)
- Involuntary movement (Dyskinesia)
- Low blood pressure (hypotension)
- Hypersensitivity reactions, sometimes severe (e.g. anaphylaxis, shortness of breath, low blood pressure, hives)
- Allergic reactions (including slight rash)
- Local inflammation at the site of injection after repeated application

Very rare side effects (probably affecting fewer than 1 in 10,000 people):

- Swelling, including swelling of the face (oedema)

If you are having **blood tests**, tell your doctor you have been given Granisetron because it sometimes causes changes in tests of liver function.

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

5. HOW TO STORE GRANISETRON

Keep out of the reach and sight of children.

Do not store above 25°C. Do not freeze.

xxxxx/27/08

-----✂-----
0.18% w/v sodium chloride and 4% glucose injection
5% w/v glucose injection
Hartmann's solution
1.87% w/v sodium lactate injection
10% mannitol injection
1.4% w/v sodium hydrogen carbonate injection
2.74% w/v sodium hydrogen carbonate injection
4.2% w/v sodium hydrogen carbonate injection

If required, Granisetron should only be diluted with one of these infusion fluids.

Granisetron must not be mixed with any other medicinal products.

For single use only. The product should be used immediately after opening the ampoule. Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C in normal indoor illumination protected from direct sunlight. From a microbiological point of view,

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

Do not use Granisetron after the expiry date which is stated on the ampoule label and the outer carton after "Exp. date". The expiry date refers to the last day of that month. Do not use Granisetron if you notice the solution is not clear or free from particles.

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 contains

The **active substance** is granisetron hydrochloride

Each 1 ml ampoule contains a total content of 1 mg granisetron as the hydrochloride in 1 ml of a sterile solution.

Each 3 ml ampoule contains a total content of 3 mg granisetron as the hydrochloride in 3 ml of a sterile solution.

The **other ingredients** are sodium chloride, citric acid monohydrate, sodium hydroxide and water for injections.

What Granisetron looks like and contents of the pack

Granisetron is a clear colourless concentrate for solution for injection or infusion.

Pack size:

Granisetron is available in packs of five or ten ampoules filled with 1 ml or 3 ml of the solution.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

hameln pharma plus gmbh
Langes Feld 13
31789 Hameln, Germany

Manufacturer:

hameln pharmaceuticals gmbh
Langes Feld 13
31789 Hameln, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

DE	Granisetron-hameln 1 mg/ml
DK	Granisetron Hameln 1 mg/ml
FI	Granisetron Hameln 1 mg/ml
NL	Granisetron-hameln 1 mg/ml
PT	Granisetron Hameln 1 mg/ml
SE	Granisetron Hameln 1 mg/ml
UK	Granisetron 1 mg/ml

This leaflet was last approved in 07/2008

the product should be used immediately. If to be stored, the dilutions should be prepared under appropriate aseptic conditions.

Do not store above 25°C. Do not freeze.

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

Any unused product or waste material should be disposed of in accordance with local requirements.

xxxxx/27/08