PACKAGE LEAFLET: INFORMATION FOR THE USER

hameln

Granisetron 1 mg/ml

concentrate for solution for injection or infusion

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet.

Active substance: Granisetron hydrochloride

What is in this leaflet:

1. What Granisetron is and what it is used for
2. What you need to know before you are given Granisetron
3. How Granisetron will be given
4. Possible side effects
5. How to store Granisetron
6. Contents of the pack and other information

1. WHAT GRANISETRON IS AND WHAT IT IS USED FOR

Granisetron 1 mg/ml concentrate for solution for injection or infusion contains a medicine called granisetron. This belongs to a group of medicines called '5-HT_3 receptor antagonists' or 'antiemetics'.

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

The solution for injection or infusion is for use in adults, adolescents and children from 2 years of age.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN GRANISETRON

Do not use Granisetron
- if you are **allergic** (hypersensitive) to granisetron or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, nurse or pharmacist before using Granisetron

Check with your doctor, nurse or pharmacist before using Granisetron if you:
- have problems with your **bowel movements** because of a blockade 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 and ondansetron used like Granisetron in the treatment and prevention of nausea and vomiting.

Serotonin syndrome is an uncommon but potentially life-threatening reaction that can occur with granisetron (see section 4). The reaction can occur if you take granisetron alone but it is more likely to occur if you take granisetron with certain other medicines (in particular fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram, venlafaxine, duloxetine).

Other medicines and Granisetron

Please tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Granisetron can affect the way some medicines work. Also some other medicines can affect the way this injection or infusion works.

In particular, tell your doctor, nurse or pharmacist if you are taking the following medicines:
- medicines used to treat an irregular heartbeat or other '5-HT_3 receptor antagonist' medicines such as dolasetron or ondansetron (see 'Warnings and precautions' above)
- phenobarbital, a medicine used to treat epilepsy.
- SSRIs (selective serotonin reuptake inhibitors) used to treat depression and/or anxiety. Examples are fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram.
- SNRIs (serotonin noradrenaline reuptake inhibitors) used to treat depression and/or anxiety. Examples are venlafaxine, duloxetine.

Pregnancy and breastfeeding

You should not have this injection or infusion if you are pregnant, trying to get pregnant or are breastfeeding, unless your doctor has told you to.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor, nurse or pharmacist for advice before taking this medicine.

Driving and using machines

Granisetron is not likely to affect your ability to drive or use any tools or machines.

Granisetron contains sodium

This medicine contains:
- a maximum of 27.7 mg (or 1.2 mmol) sodium (main component of cooking/table salt) per 1 ml ampoule. This is equivalent to 1.4% of the recommended maximum daily dietary intake of sodium for an adult
- a maximum of 83.1 mg (or 3.6 mmol) sodium (main component of cooking/table salt) per 3 ml ampoule. This is equivalent to 4.2% of the recommended maximum daily dietary intake of sodium for an adult

3. HOW GRANISETRON WILL BE GIVEN

The injection or infusion will be given to you by a doctor or nurse. The dose of Granisetron 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 or infusion into the veins (intravenous).

Dosage

The usual doses are:

Prevention of feeling or being sick following radio- or chemotherapy

You will be given the injection or infusion before your radio- or chemotherapy starts. The injection or infusion into your veins will take between 30 seconds (injection) and 5 minutes (infusion) 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 or infusion will take between 30 seconds (injection) and 5 minutes (infusion) and the dose will usually be between 1 and 3 mg. The medicine may be diluted before it is injected or infused into your veins. You may be given more injections or infusions to stop your sickness after the first dose. There will be at least 10 minutes between each dose. The most Granisetron you will be given is 9 mg a day.

Combination with steroids

The effect of the injection or infusion 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 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 chemotherapy

Children will be given Granisetron by infusions into a vein as described above with the dose depending on the child's weight. The infusions will be diluted and be given before 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 more Granisetron than you should

Because the injection or infusion 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.

For information intended for healthcare professionals please see accordant section below.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice the following problem 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 up to 1 in 10 users):
- Difficulty in sleeping (insomnia)
- Diarrhoea
- Changes in how your liver is working shown by blood tests

Uncommon (affects up to 1 in 100 users):
- Skin rashes or an allergic skin reaction or "nettle-rash" or "hives" (urticaria). The signs may include red, raised itchy bumps.
- Abnormal involuntary movements, such as shaking, muscle rigidity and muscle contractions
- Changes in the heartbeat (rhythm) and changes seen on ECG readings (electrical recordings of the heart)

The following information is intended for healthcare professionals only:

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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.

1. 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.

2. 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 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

0.18% w/v sodium chloride and 4% glucose injection

5% w/v glucose injection

- Serotonin Syndrome. The signs may include diarrhoea, nausea, vomiting, high temperature and blood pressure, excessive sweating and rapid heartbeat, agitation, confusion, hallucination, shivering, muscles shakes, jerks or stiffness, loss of coordination and restlessness.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme – website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE GRANISETRON

Keep this medicine out of the sight and reach of children.

This product does not require any special temperature storage conditions.

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

Do not use this medicine after the expiry date which is stated on the ampoule label and the outer carton after "EXP.". The expiry date refers to the last day of that month.

Do not use this medicine if you notice the solution is not clear or free from particles.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER 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 ltd
Nexus, Gloucester Business Park
Gloucester, GL3 4AG, United Kingdom

Manufacturer:
Siegfried Hameln GmbH
Langes Feld 13
31789 Hameln, Germany

hameln rds s.r.o.
Horná 36,
90001 Modra, Slovakia

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	Granissetrom Hameln 1 mg/ml
SE	Granisetron Hameln 1 mg/ml
UK	Granisetron 1 mg/ml

This leaflet was last revised in 03/2026

46170/12/26

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, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 -8°C, unless dilution has taken place in controlled and validated aseptic conditions.

This product does not require any special temperature storage conditions.

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.