

Package leaflet: Information for the user

Granisetron 1 mg film-coated tablets

Read all of this leaflet carefully before you start taking 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 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 you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Granisetron is and what it is used for

Granisetron belongs to a group of medicines known as ‘5-HT₃ receptor antagonists’ or anti-emetics or anti-sickness medicines. These tablets are only for use in adults. It is used to prevent or treat nausea (feeling sick) and vomiting (being sick) caused by other medical treatments, such as chemotherapy or radiation treatment for cancer.

2. What you need to know before you take Granisetron

Do not take granisetron

- if you are allergic (hypersensitive) to granisetron or any of the other ingredients of this medicine (listed in section 6). If you are not sure, talk to your doctor, nurse or pharmacist before taking these tablets.

Warnings and precautions

Talk to your doctor, nurse or pharmacist before taking Granisetron, especially if you:

- have a blockage in the intestine (gut) causing symptoms such as stomach ache, wind, feeling or being sick, or difficulty passing stools.
- 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-HT₃ receptor antagonist’ medicines. These include dolasetron, ondansetron used like granisetron in the treatment and prevention of nausea and vomiting.
- the use of Buprenorphine together with Granisetron can lead to serotonin syndrome, a potentially life-threatening condition (see ‘Other medicines and Granisetron’).

Serotonin Syndrome is an uncommon but potentially life-threatening reaction that can occur with granisetron (see section 4). It can cause serious changes in how your brain, muscles, and digestive system work. The

reaction can occur if you take granisetron alone but is more likely to occur if you take granisetron with certain other medicines (in particular fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram, venlafaxine, duloxetine). Be sure to tell your doctor, nurse or pharmacist all the medicines you are taking.

Children

Children should not take these tablets.

Other medicines and granisetron

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

This is because granisetron can affect the way some medicines work. Also some other medicines can affect the way these tablets work.

In particular, tell your doctor or pharmacist if you are taking the following medicines:

- medicines used to treat an irregular heartbeat, other '5-HT₃ receptor antagonist' medicines such as dolasetron or ondansetron (see "Warnings and precautions" above)
- 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.
- Buprenorphine/opioids. These medicines may interact with granisetron and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

Pregnancy and breast-feeding

You should not take these tablets if you are pregnant, trying to get pregnant or are breast-feeding, unless your doctor has told you to.

If you are pregnant or breast-feeding, 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 should not affect your ability to drive or operate machinery.

Granisetron tablets contain lactose

This medicine contains **lactose** (a type of sugar). If your doctor has told you that you have an intolerance to some sugars, such as lactose, contact your doctor before taking this medicine.

Granisetron is essentially 'sodium free' as it contains less than 1 mmol sodium (23 mg) per dose (2 mg).

3. How to take Granisetron

Always take Granisetron exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Swallow the tablets with a glass of water.

The recommended 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.

Prevention of feeling or being sick

Your first dose of granisetron will usually be given an hour before your radio- or chemotherapy. The dose will be either one or two 1 mg tablets or one 2 mg tablet once a day for up to a week after your radio- or chemotherapy.

Treatment of feeling or being sick

The dose will usually be either one or two 1 mg tablets or one 2 mg tablet once a day, but your doctor may decide to increase your dose to up to nine 1 mg tablets a day.

Your doctor may also give you another medicine called dexamethasone to take as well.

Children

Granisetron is not suitable for children.

If you take more Granisetron than you should

Contact your doctor or go to the nearest hospital casualty department **immediately**. Take the container and any remaining tablets with you. The symptoms of overdose include mild headaches. You will be treated depending on your symptoms.

If you forget to take Granisetron

If you think you have forgotten to take your medicine speak to your doctor or nurse. Do not take two doses together to make up for the one you have missed.

If you stop taking Granisetron

Do not stop taking your medicine before the treatment is finished. If you do stop taking your medicine, your symptoms may return. Speak to your doctor first if you wish to stop taking this medicine.

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

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: may affect more than 1 in 10 people

- Headache
- Constipation. Your doctor will monitor your condition.

Common: may affect up to 1 to 10 people

- Problems sleeping (insomnia)
- Changes in how your liver is working shown by blood tests
- Diarrhoea.

Uncommon: may affect up to 1 in 100 people

- 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.
- 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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.

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

Do not store above 30°C.

Do not throw away any medicines 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. Contents of the pack and other information

What Granisetron contains

- The active substance is 1 mg of granisetron, as hydrochloride.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, hypromellose, sodium starch glycolate, magnesium stearate, titanium dioxide (E171), macrogol and polysorbate.

What Granisetron looks like and contents of the pack

Your medicine comes as a film-coated tablet. The tablets are white to off-white. The 1 mg strength tablets are marked 'GS' on one side.

Granisetron is available in blister packs of 1, 2, 4, 5, 6, 7, 10, 14, 20, 28, 30, 50, 90, 100, 150, 200, 250 and 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan
Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

Manufacturers

Generics [UK] Limited
Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

Gerard Laboratories
35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Viatrix UK Healthcare Limited
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