

GRANISETRON 3 mg/3 ml Solution for Injection
Granisetron hydrochloride

DEVATIS

Consumer Medicine Information (CMI)

What is in this leaflet

Please read this leaflet carefully before you start using GRANISETRON Solution for Injection.

This leaflet answers some common questions about GRANISETRON Solution for Injection. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given GRANISETRON Solution for Injection against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, talk to your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What GRANISETRON Solution for Injection is used for

GRANISETRON 3 mg/3 ml Solution for Injection contains granisetron (as granisetron hydrochloride) as the active ingredient.

Granisetron injection belongs to a group of medicines called anti-emetics.

Granisetron injection is given to stop you feeling sick (nauseous) or being sick (vomiting). It is especially useful when you need to have medical treatment that may cause you to feel or be sick, for example, chemotherapy, radiotherapy or surgery.

Your doctor may have prescribed GRANISETRON Solution for Injection for another reason.

Ask your doctor if you have any questions about why GRANISETRON Solution for Injection has been prescribed for you.

This medicine is available only with a doctor's prescription.
There is no evidence that it is addictive.

Before you use GRANISETRON Solution for Injection

When you must not use it

You must not be given GRANISETRON Solution for Injection if you have had an allergic reaction to:

- any medicine containing granisetron
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or breathing difficulty; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

If you are not sure whether you should be given Granisetron Solution for Injection, talk to your doctor.

Before you start to use it

Tell your doctor if:

- **You have allergies to any other medicines, foods, preservatives or dyes.**
You have had an allergic reaction with other medicines used to prevent or treat nausea and vomiting, such as ondansetron and tropisetron. You may have an allergic reaction to Granisetron injection as well.
- **You have severe constipation.**
- **You are pregnant or plan to become pregnant or are breastfeeding.**
Your doctor can discuss with you the risks and benefits of using Granisetron injection while you are pregnant or breast-feeding.
- **You have been given granisetron before, and you became unwell.**
You may need to be given another medicine instead.
- **You have a heart condition related to changes in the rhythm or rate of your heart beat.**

If you have not told your doctor about any of the above, tell them before you start being given GRANISETRON Solution for Injection.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking GRANISETRON Solution for Injection.

Some medicines may interfere with GRANISETRON Solution for Injection. These include:

- Phenobarbitone (a medicine used to treat epilepsy)

Phenobarbitone may be affected by Granisetron injection or may affect how well Granisetron injection works. You may need different amounts of your medicine, or you may need to take a different medicine.

- Medicines that can affect the serotonin levels in your body.

These may include: some antibiotics, medicines used to treat depression, medicines that treat or prevent pain, some medicines to treat Parkinson's disease, medicines to treat obesity; and medicines used to treat attention hyperactivity disorder.

These medicines may be affected by GRANISETRON Solution for Injection, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking GRANISETRON Solution for Injection.

How to use GRANISETRON Solution for Injection

How much to use

Your doctor will decide what dose and how long you will receive GRANISETRON Solution for Injection. This depends on your condition and other factors, such as your weight.

How it is given

GRANISETRON Solution for Injection is given as a fast or slow injection into a vein (intravenous 'drip'). It must only be given by a nurse or doctor.

GRANISETRON Solution for Injection must only be prepared and given by a doctor or nurse.

While you are using GRANISETRON 3 mg/3 ml Solution for Injection

Things you must do

Tell any other doctors, dentists and pharmacists who are treating you that you are being given GRANISETRON Solution for Injection, especially if you are about to be started on any new medicines.

Tell your doctor immediately if you become pregnant while you are being given GRANISETRON Solution for Injection.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take any other medicines whether they require a prescription or not without first telling your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Granisetron injection affects you.

Be careful when drinking alcohol while you are being given Granisetron injection.

Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are being given Granisetron injection.

If you drink alcohol, dizziness or light-headedness may be worse.

In case of overdose

If you are given too much (overdose)

As GRANISETRON 3 mg/3 ml Solution for Injection is given to you in a hospital under the supervision of your doctor, it is very unlikely that you will receive an overdose.

However, if you experience severe side effects tell your doctor immediately. Symptoms of an overdose may include the side effects listed below in the 'Side Effects' section but are usually of a more severe nature.

However, if this is the case, immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much GRANISETRON 3 mg/3 ml Solution for Injection.

Do this even if there are no signs of discomfort or poisoning.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being treated with GRANISETRON Solution for Injection.

This medicine helps most people with nausea and vomiting, but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Tell your doctor or nurse if you notice any of the following side effects and they worry you:

- headache
- unusual tiredness or weakness
- dizziness or light-headedness
- nervousness
- drowsiness
- difficulty in sleeping
- abdominal pain
- constipation
- diarrhea
- altered taste
- fever
- skin rash

The above list includes the more common side effects of your medicine.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following symptoms:

- chest pain
- changes in your heart beat
- severe dizziness or fainting
- seizures
- symptoms of serotonin syndrome such as fever, sweating, fast heartbeat, agitation or confusion and loss of muscle coordination, which may lead to loss of consciousness
- symptoms of an allergic reaction, such as shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

The above list includes very serious side effects. You may need urgent medical attention or hospitalization. These side effects are rare.

Tell your doctor if you notice anything else that is making you feel unwell, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

After using GRANISETRON Solution for Injection

Storage

Keep the ampoule in the outer carton in order to protect from light. Granisetron injection ampoules should be stored below 30°C.

Keep this medicine where children cannot reach them.

A locked cupboard at least one and a half meters above the ground is a good place to store medicines.

Disposal

Do not use GRANISETRON Solution for Injection after the expiry date, which is stated on the packaging.

If your doctor advises you to stop taking GRANISETRON Solution for Injection or the medicine has passed its expiry date, ask your pharmacist how to throw away medicines you no longer use. Do not throw away any medicines via wastewater. These measures will help protect the environment.

Product description

What it looks like

Granisetron injection is a clear solution for injection in a glass ampoule. Granisetron ampoules for injection come in the following pack sizes:

3 mg/3 ml: packs containing 1 or 5 ampoules

Not all pack sizes may be currently marketed.

Ingredient

Active ingredient(s):

Each 3 ml vial contains 3 mg of granisetron (as granisetron hydrochloride).

Inactive ingredients:

- sodium chloride
- citric acid monohydrate
- sodium hydroxide
- hydrochloric acid
- water for injections

GRANISETRON Solution for Injection does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Sponsor

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