Granisetron Sandoz®

granisetron (as hydrochloride) injection

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Granisetron Sandoz.

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 taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT GRANISETRON SANDOZ IS USED FOR

This medicine is used stop nausea (feeling sick) and vomiting which can occur after some treatments such as chemotherapy or radiotherapy.

It contains the active ingredient granisetron. Granisetron belongs to a group of medicines called serotonin 5-HT₃ receptor antagonists. It is an anti-emetic.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

BEFORE YOU ARE GIVEN GRANISETRON SANDOZ

When you must not be given it

Do not take this medicine if you an allergy to:

 granisetron, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description

Some of the symptoms of an allergic reaction may include:

- 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.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

severe constipation

 heart condition related to changes in the rhythm or rate of your heart beat

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking Granisetron Sandoz.

If you are not sure whether you should be given Granisetron
Sandoz or have become unwell if previously given Granisetron
Sandoz, talk to you doctor as there may be an alternative medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Granisetron Sandoz may interfere with each other. These include:

• phenobarbitone, a medicine used to treat epilepsy.

This medicine may be affected by Granisetron Sandoz or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

HOW GRANISETRON SANDOZ IS GIVEN

How much is given

The dose of Granisetron Sandoz you will receive depends on your medical condition and other factors such as your weight.

How it is given

Granisetron Sandoz is usually administered in a hospital as an injection into a vein. It will be given by a doctor or nurse.

If you receive too much (overdose)

Granisetron Sandoz is usually administered in a hospital, under the supervision of a doctor. Therefore it is unlikely that you will receive too much. However, you should tell your doctor or nurse immediately if you feel unwell at all whilst you are being given Granisetron Sandoz. You may need urgent medical attention.

Symptoms of an overdose may include the side effects listed below in the 'Side Effects' section but are usually of a more severe nature.

WHILE YOU ARE BEING GIVEN GRANISETRON SANDOZ

Things you must do

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while you are being treated with Granisetron Sandoz, tell your doctor immediately.

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 without first telling your doctor.

Things to be careful of

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

This medicine may cause drowsiness or sleepiness in some people.

Be careful of drinking alcohol while you are being given this medicine.

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

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being treated with Granisetron Sandoz.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache
- unusual tiredness or lightheadedness
- agitation
- nervousness
- drowsiness
- difficulty in sleeping
- abdominal pain
- constipation
- diarrhoea
- altered taste
- fever
- skin rash.

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

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- chest pain
- changes in your heart beat
- · severe dizziness or fainting
- 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 hospitalisation. These side effects are rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

AFTER USING GRANISETRON SANDOZ

Storage

Granisetron Sandoz will be stored in the pharmacy or on the ward. The ampoules are kept in a cool dry place protected from light where the temperatures stay below 25°C.

PRODUCT DESCRIPTION

What it looks like

Granisetron Sandoz injection is a clear, colourless to slightly yellow solution. It is supplied in packs of 1 and 5 clear glass vials.

Ingredients

Active ingredients:

- Granisetron Sandoz 3mg/3mL -3mg granisetron (as granisetron hydrochloride)
- Granisetron Sandoz 1mg/1mL -1mg granisetron (as granisetron hydrochloride)

Inactive ingredients:

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

This medicine does not contain lactose or gluten.

Supplier

Sandoz Pty Ltd

ABN 60 075 449 553 Level 2, 19 Harris St Pyrmont NSW 2009 Tel: 1800 634 500

Novartis New Zealand Ltd

Private Bag 65904 Mairangi Bay Auckland 0754 New Zealand Tel: 0800 354 335

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Australian Register Numbers

Granisetron Sandoz 3mg/3ml injection: AUST R 173996 Granisetron Sandoz 1mg/1ml injection: AUST R 173995