
PATIENT INFORMATION LEAFLET**SCHEDULING STATUS**

S4

GRANTRYL 1 mg/1 ml injection**GRANTRYL 3 mg/3 ml injection****Granisetron****Sugar free**

Read all of this leaflet carefully before GRANTRYL is administered to you

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

GRANTRYL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What GRANTRYL is and what it is used for

GRANTRYL 1 mg/1 ml:

The active substance is granisetron 1 mg (as hydrochloride) in 1 ml aqueous solution per ampoule.

GRANTRYL 3 mg/3 ml:

The active substance is granisetron 3 mg (as hydrochloride) in 3 ml aqueous solution per ampoule.

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

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

2. What you need to know before GRANTRYL is administered to you

You should not receive GRANTRYL:

- If you are hypersensitive (allergic) to granisetron hydrochloride or any of the other ingredients of GRANTRYL;
- GRANTRYL should not be given to children under 2 years;
- If you are pregnant, trying to get pregnant or breast-feeding, unless your doctor has told you to;
- If you have an inherited disorder of the heart's electrical activity (known as "long QT syndrome"). Ask your doctor if you are unsure if you have this.

Warnings and precautions

Tell your doctor or healthcare professional before being given GRANTRYL if you–

- have problems with your bowel movements because of a blockade in your gut (intestines), as your condition may become worse;
- have heart problems with rapid or irregular heart beats;
- are being treated with medicines to control your heart beat; or
- if you have problems with the levels of salts in your body, such as potassium, sodium or calcium (electrolyte abnormalities).

Other medicines and GRANTRYL

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of GRANTRYL with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

Always tell your doctor, pharmacist or other healthcare professional if you are taking any other medicines. (This includes complementary or traditional medicines). This is particularly important if you are using or receiving phenobarbital, a medicine used to treat epilepsy.

Pregnancy and breastfeeding and fertility:

If you are pregnant, planning to become pregnant, or are breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before receiving GRANTRYL.

Driving and using machines:

It is not always possible to predict to what extent GRANTRYL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which GRANTRYL affects them.

If you feel drowsy or your vision is blurred, you should not drive or operate any tools or machines.

Important information about some of the ingredients of GRANTRYL:

GRANTRYL is sugar free.

3. How GRANTRYL will be administered

GRANTRYL will be administered to you exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure. If you have the impression that GRANTRYL is too strong or weak for you, talk to your doctor or pharmacist, as soon as possible.

Do not share medicines prescribed for you with any other person.

GRANTRYL is only for intravenous use, i.e. by injection or infusion directly into a vein.

You will not be expected to give yourself GRANTRYL.

GRANTRYL will be given to you by a doctor or a nurse. It will be given to you as a slow injection into one of your veins or through a tube into one of your veins (called an "intravenous infusion"). The injection usually takes 30 seconds and the infusion usually takes 5 minutes.

If you receive more GRANTRYL than you should

A healthcare professional will administer GRANTRYL and control the dosage according to your doctor's instructions.

In the unlikely event of receiving an overdose your doctor will manage the overdosage.

If you have any concerns about receiving an overdose, please talk to your doctor.

If you missed a dose of GRANTRYL

Because GRANTRYL will be given to you by a doctor or a healthcare professional, it is unlikely that you will miss a dose. However, if you are worried talk to your doctor or healthcare professional.

Do not receive a double dose to make up for forgotten individual doses.

4. Possible side effects

GRANTRYL can have side effects.

Not all side effects reported for GRANTRYL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving GRANTRYL, please consult your doctor, pharmacist or other healthcare professional for advice.

If you have any of the following very serious side effects, tell your doctor straight away - you need urgent medical attention:

- Swelling of the throat, face, lips and mouth, difficulty in breathing or swallowing.
You may have a serious allergic reaction (anaphylaxis).
- rash or itching,
- fainting

This very serious allergic reaction occurs less frequently.

Tell your doctor straight away if you notice any of the following serious side effects - you may need urgent medical attention:

- A severe, crushing chest pain (angina), fainting, fast or irregular heart- beat.

- sudden chest pain or chest tightness
- Difficulty seeing well.
- Frequent urination with burning urine. These may signs of an urinary tract infection.
- Abnormal (uncontrollable) body movements with or without eye-rolling

These serious side effects occur less frequently or at unknown frequency.

Check with your doctor, pharmacist or healthcare professional if any of these side effects persist or become bothersome:

Frequent side effects

- Stomach pain, constipation, hiccups
- Unusual tiredness or weakness

Less frequent side effects

- Anxiety, drowsiness or sleeping problems
- Headache, dizziness, restlessness
- Indigestion, unusual taste in mouth
- Skin rashes
- Hot flushes, high blood pressure, low blood pressure. You will only know for sure you have blood pressure problems if you have your blood pressure measured.
- Fever (body temperature of 38 °C or more), pain and irritation at injection site.

Frequency not known:

- Infections.

- Blood disorders like anaemia (too few red blood cells or their haemoglobin content is too low) or leukocytosis (high number of white cells in blood). You will only know this if your blood is tested. Tell your doctor if you feel unusually tired, weak or feverish or if you bleed or bruise easily.

If you notice any side-effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of GRANTRYL.

Acino Pharma (Pty) Ltd: E-mail: drugsafety_za@acino.swiss Tel: 060 998 7896

By reporting side effects, you can help provide more information on the safety of GRANTRYL.

5. How to store GRANTRYL

Store in the original packaging at or below 30 °C. Protect from light.

Diluted solution:

Use immediately after reconstitution. Solutions should not be stored for longer than 24 hours at a temperature of 2 – 8 °C unless prepared under controlled aseptic conditions. Any unused solution should be discarded after 24 hours.

Do not store your medicine in the bathroom.

Do not use GRANTRYL after the expiry date printed on the label or carton.

Return any expired or unused medicine to your pharmacist for safe disposal.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What GRANTRYL contains

The active substance is granisetron hydrochloride

The other ingredients are citric acid monohydrate, sodium citrate, sodium chloride, water for injection and nitrogen

What GRANTRYL looks like

GRANTRYL 1 mg/1 ml: A clear colourless solution in a clear Type 1 glass ampoule.

GRANTRYL 3 mg/3 ml: A clear colourless solution in a clear Type 1 glass ampoule.

Contents of the pack

GRANTRYL 1 mg/1 ml: Packs of 5 x 1 ml Type I glass ampoules, packed in a PVC tray, contained in a cardboard carton

GRANTRYL 3 mg/3 ml: Packs of 5 x 5 ml Type I glass ampoules, packed in a PVC tray, contained in a cardboard carton

Holder of Certificate of Registration

Acino Pharma (Pty) Ltd

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