**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS**

**S4**

**GRANTRYL 1 mg film-coated tablets**

**Granisetron**

**Contains sugar: Lactose anhydrous 69,38 mg**

**GRANTRYL 2 mg film-coated tablets**

**Granisetron**

**Contains sugar: Lactose anhydrous 138,76 mg**

**Read all of this leaflet carefully before you start taking GRANTRYL**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- 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 belongs to a group of medicines called 5-HT3 receptor antagonists which act as anti-emetics (used to prevent nausea and vomiting).

GRANTRYL is used to prevent nausea (feeling sick) and vomiting (being sick), after having medical treatments that may cause you to feel or be sick, for example, chemotherapy or radiotherapy for cancer.

## 2. What you need to know before you take GRANTRYL

**Do not take GRANTRYL:**

- if you are hypersensitive (allergic) to granisetron, or any of the other ingredients of GRANTRYL (listed in section 6).
- if you are hypersensitive (allergic) to any related medicines (other 5-HT3 receptor antagonists), such as ondansetron and dolasetron.
- if you have heart disorders such as congenital long QT syndrome.
- if you are pregnant or breastfeeding.
- if your child is under the age of 2 years.

**Warnings and precautions**

Take special care with GRANTRYL:

- if you have been told by a doctor that your bowels don’t work properly or if you are having problems with your bowel movements because of a blockage in your gut (intestines).
- if you have any pain in your abdomen (stomach) or if your abdomen feels distended or swollen.
- if you have severe constipation.
- if you have heart problems (e.g. dysrhythmias or cardiac conduction disorders), 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, magnesium, sodium or calcium, in your body (electrolyte abnormalities).

- if you are taking any other 5-HT3 receptor antagonist medicines. These include dolasetron or ondansetron also used in the treatment and prevention of nausea and vomiting.
- if you are taking other medicines that increase the level serotonin in your body or buprenorphine, as the use of these medicines together with GRANTRYL can lead to serotonin syndrome. Serotonin syndrome is a potentially life-threatening reaction that can occur with GRANTRYL. It can cause serious changes in how your brain, muscles, and digestive system work. The reaction can occur if you take GRANTRYL alone but is more likely to occur if you take GRANTRYL 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**

GRANTRYL should not be given to children under the age of 2 years.

**Other medicines and GRANTRYL**

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Medicines used to treat an irregular heartbeat such as beta-blockers or calcium channel blockers.
- Other 5-HT3 receptor antagonist medicines such as dolasetron or ondansetron.
- Phenobarbitone, used to treat epilepsy.
- Ketoconazole, used to treat fungal infections.

- SSRIs (selective serotonin reuptake inhibitors) or SNRIs (serotonin noradrenaline reuptake inhibitors), used to treat depression and/or anxiety including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram, venlafaxine, duloxetine.
- Buprenorphine/opioids. These medicines may interact with GRANTRYL 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, fever (serotonin syndrome).
- Tramadol, used to help relieve moderate to moderately severe pain.

**GRANTRYL with food**

GRANTRYL may be taken with or without food.

**Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

You should not take GRANTRYL if you are pregnant or breastfeeding your baby.

**Driving and using machinery**

Since adverse reactions such as headache, dizziness, drowsiness and blurred vision have been reported in patients receiving GRANTRYL, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that GRANTRYL does not adversely affect your ability to do so.

It is not always possible to predict to what extent GRANTRYL may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which GRANTRYL affects you (see section 4).

**GRANTRYL contains lactose**

which may have an effect on the control of your blood sugar if you have diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

## 3. How to take GRANTRYL

Always take GRANTRYL exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

*Chemotherapy Induced Nausea and Vomiting (CINV)*

*Prevention:*

The usual dose of GRANTRYL is 1 mg twice a day or 2 mg once a day, for up to one week following chemotherapy. The first dose of GRANTRYL should be administered within one hour before the start of chemotherapy.

*Radiotherapy Induced Nausea and Vomiting (RINV)*

The usual dose of GRANTRYL is 2 mg once a day, for up to one week following radiotherapy. The first dose of GRANTRYL should be administered within one hour before the start of therapy.

Your doctor will tell you how long your treatment with GRANTRYL will last.

If you have the impression that the effect of GRANTRYL is too strong or too weak, tell your doctor or pharmacist.

**If you take more GRANTRYL than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Headaches are a symptom of overdose.

**If you forget to take GRANTRYL**

Do not take 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 taking GRANTRYL, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking GRANTRYL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to GRANTRYL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- serotonin syndrome. The signs may include fever, sweating, shivering, diarrhoea, nausea, vomiting, muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination, fast heartbeat, changes in blood pressure, confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness and coma,
- chest pain,
- sudden chest pain or chest tightness
- changes in the way your heart beats, for example, if you notice it beating fast or irregular heartbeats,

- changes seen on ECG readings (electrical recordings of the heart),
- seizures (fitting).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache,
- constipation, diarrhoea, abdominal (stomach) pain, nausea (feeling sick), vomiting (being sick), hiccups,
- problems sleeping (insomnia),
- changes in how your liver is working (shown by blood tests).

Less frequent side effects:

- abnormal body movements, including prolonged involuntary upward deviation of the eyes or involuntary muscle contractions that cause repetitive or twisting movements, shaking or muscular stiffness,
- excess sleepiness (somnolence), drowsiness, dizziness, agitation, anxiety,
- indigestion, taste disturbances,
- high blood pressure, low blood pressure.

Side effects with an unknown frequency:

- infections including urinary tract infection,
- visual disturbances such as blurred vision,
- ever, fatigue, weakness or loss of strength (asthenia),
- low levels of red blood cells, with symptoms of unusual tiredness, dizziness, pale skin (anaemia),

- increased number of white blood cells in the blood with symptoms of persistent fever, night sweats and loss of weight (leukocytosis).

If you notice any side effects not mentioned in this leaflet, please inform 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: https://www.sahpra.org.za/health-products-vigilance/

**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 all medicines out of reach of children.

Store at or below 25 °C protected from light and moisture.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

GRANTRYL contains:

GRANTRYL 1 mg

The active substance is 1,0 mg of granisetron as granisetron hydrochloride.

The other ingredients are hypromellose, lactose anhydrous, macrogol, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, sodium starch glycolate, talc,

titanium dioxide (C.I. 77891).

Contains sugar: Lactose anhydrous 69,38 mg

GRANTRYL *2 mg*

The active substance is 2,0 mg of granisetron as granisetron hydrochloride.

The other ingredients are hypromellose, lactose anhydrous, macrogol, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, sodium starch glycolate, talc, titanium dioxide (C.I. 77891).

Contains sugar: Lactose anhydrous 138,76 mg

**What GRANTRYL looks like and contents of the pack**

GRANTRYL 1 mg: Triangular, white, biconvex film-coated tablets, with ‘G1’ engraved on one side OR triangular, white, biconvex film-coated tablets, with “C” debossed on one side and “45” debossed on the other side.

GRANTRYL 2 mg: Triangular, white, biconvex film-coated tablets, with ‘G2’ engraved on one side OR triangular, white, biconvex film-coated tablets, with “C” debossed on one side and “46” debossed on the other side.

1, 5, 10 and 100 film-coated tablets are packed into white opaque polyvinyl chloride film blister strip sealed with an aluminium foil backing. The blisters will be placed in an outer cardboard carton along with a printed leaflet.

Not all pack sizes are necessarily marketed.

**Holder of Certificate of Registration**

Acino Pharma (Pty) Ltd

106 16th Road

Midrand,

1686

**This leaflet was last revised in**

24 November 2022

**Registration numbers**

GRANTRYL 1 mg: 42/5.7.2/1007

GRANTRYL 2 mg: 42/5.7.2/1008

**Access to the corresponding Professional Information**

TBA

GRANTRYL 2 mg:

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|---|
| Namibia: NS2 10/5.7.2//0622 |