Patient Information Leaflet

GRANICIP 1 mg (TABLETS)

GRANICIP 2 mg (TABLETS)

SCHEDULING STATUS: S4

GRANICIP 1 mg (Tablets)

Granisetron.

Contains sugar: Lactose monohydrate 37,50 mg

GRANICIP 2 mg (Tablets)

Granisetron.

Contains sugar: Lactose monohydrate 75 mg

Read all of this leaflet carefully before you start taking GRANICIP

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- GRANICIP 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 GRANICIP is and what it is used for
2. What you need to know before you take GRANICIP
3. How to take GRANICIP
4. Possible side effects

5. How to store GRANICIP
6. Contents of the pack and other information.

1. What GRANICIP is and what it is used for

GRANICIP belongs to a group of medicines known as anti-emetics and anti-vertigo preparations. Anti-emetic medication relieves nausea and vomiting and anti-vertigo medication is indicated for the treatment of dizziness or vertigo.

GRANICIP tablets are indicated for the prevention of nausea and vomiting caused by medical treatments for cancer, such as chemotherapy and radiotherapy.

2. What you need to know before you take GRANICIP

Do not take or give your child GRANICIP:

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

Warnings and precautions

Take special care with GRANICIP:

- if you have problems with your bowel movements. GRANICIP may reduce the motility of your colon (large bowel) thus causing stool and fluids to pass more slowly through it. Your

doctor will monitor you for signs and symptoms of bowel obstruction, which include abdominal discomfort and bloating, loss of appetite, vomiting and inability to pass stool.

- 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 GRANICIP can lead to serotonin syndrome. Serotonin syndrome is a potentially life-threatening reaction that can occur with GRANICIP. It can cause serious changes in how your brain, muscles, and digestive system work. The reaction can occur if you take GRANICIP alone but is more likely to occur if you take GRANICIP 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.

Other medicines and GRANICIP

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

GRANICIP has been safely used in combination with a variety of other medicines commonly prescribed in conjunction with anti-nausea treatments. These include medicines for the treatment

of anxiety and sleeplessness, mental health problems and stomach ulcers. In addition GRANICIP has also been safely administered with pain killers and medicines used during anaesthesia. However, if you are taking other medicines on a regular basis, use of GRANICIP with other medicines may cause undesirable interactions.

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 GRANICIP 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.

GRANICIP with food

GRANICIP may be taken with or without food.

Pregnancy, breastfeeding and fertility

The safety of GRANICIP in pregnancy and lactation (breast feeding) has not been established. Thus use in pregnancy and lactation is contraindicated (see **Do not take or give your child GRANICP)**.

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

Driving and using machinery

There have been reports of excessive sleepiness in patients taking GRANICIP and this may affect your ability to drive or operate machinery. If you experience excessive sleepiness while taking GRANICIP, you should refrain from these activities.

GRANICIP contains lactose

GRANICIP contains lactose, which is a type of sugar. 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 GRANICIP

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

Always take GRANICIP exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Chemotherapy induced nausea and vomiting (CINV) prevention

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

Radiotherapy induced nausea and vomiting (RINV) prevention

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

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

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

Use in children

GRANICIP is contraindicated in children under the age of 2 years (see **Do not take or give your child GRANICIP**).

Safety and efficacy in of GRANICIP in the prevention of radiotherapy-induced nausea and vomiting (RINV) in children has not been established.

Use in elderly

Although available information indicates that it is not necessary to adjust the dosage of GRANICIP in elderly patients, care is advised in elderly patients and patients with kidney or liver impairment. Please discuss this with your treating doctor if you are unsure.

If you take more GRANICIP than you should

In the event of an overdosage, or if someone else has taken your medicine by mistake, you, or this other person, may experience any of the side-effects listed below, including headache.

There is no specific antidote for GRANICIP.

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, seek

help at the nearest hospital or poison control centre.

If you forget to take GRANICIP

Take GRANICIP as prescribed. If you miss a dose, take it as soon as you remember. However, do not take a double dose (two doses at the same time) to make up for the forgotten dose.

4. Possible side effects

GRANICIP may have side effects.

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

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

- Hypersensitivity or allergic reactions, such as rash, swelling and difficulty breathing.

These are all very serious side effects. If you have them, you may have had a serious reaction to GRANICIP. 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:

- Bowel obstruction, which may present as difficulty in passing stool, nausea and vomiting, and loss of appetite with a swollen or distended stomach.

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

Tell your doctor if you notice any of the following:

- Headache, fainting, agitation, dizziness, drowsiness or sleeplessness.

- Palpitations and chest pain.
- Constipation, stomach pain, diarrhoea (runny stomach), stomach discomfort, unusual taste and loss of appetite.
- Hair loss.
- Unusual tiredness or weakness.
- Fever.
- Increased or decreased heart rate.

Should you experience any of these side-effects, you may want to discuss them with your treating doctor, especially if they become bothersome or intolerable.

While receiving treatment with GRANICIP, you may develop:

- Low white blood cell counts.
- Low red blood cell counts (anaemia).
- Low platelet counts.
- Raised levels of liver enzymes.

Your doctor will monitor you for these side-effects.

Side effects with an unknown frequency:

- Myocardial ischemia

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 via the “6.04 Adverse Drug Reaction Reporting Form”, found online under

SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of GRANICIP.

5. How to store GRANICIP

Store all medicines out of reach of children.

Store at or below 25 °C in a cool dry place. Protect from light.

Keep the blisters in the outer carton until required for use.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

6. Contents of the pack and other information

What GRANICIP contains

The active ingredient in GRANICIP is granisetron.

GRANICIP 1 mg: Each film-coated tablet contains granisetron hydrochloride equivalent to 1 mg granisetron.

GRANICIP 2 mg: Each film-coated tablet contains granisetron hydrochloride equivalent to 2 mg granisetron.

The other ingredients are lactose monohydrate, microcrystalline cellulose (Avicel PH 101), sodium starch glycollate (Primojel B), maize starch and magnesium stearate.

Film coating GRANICIP 1 mg and GRANICIP 2 mg

Opadry 04F58804 white: hydroxy propyl methyl cellulose, titanium dioxide (C.I. 77891), polyethylene glycol.

What GRANICIP looks like and contents of the pack

GRANICIP 1 mg:	White to off-white barrel-shaped, film-coated biconvex tablet with 'G1' debossed on one side and plain on the other.
GRANICIP 2 mg:	White to off-white barrel-shaped, film-coated biconvex tablet with 'G2' debossed on one side and plain on the other.

GRANICIP 1 mg:	Tablets in PVC film-aluminium foil blister strips in an outer carton in packs of 5 or 10 tablets.
GRANICIP 2mg:	Tablets in PVC film-aluminium foil blister strips in an outer carton in packs of 5 or 10 tablets.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

Building 9,

Parc du Cap

Mispel Street,

Bellville,

7530

Customer Care: 080 222 6662

This leaflet was revised in

29 May 2023

Registration number(s)

GRANICIP 1 mg:	41/5.7.2/0397
GRANICIP 2 mg:	41/5.7.2/0398

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.