1.3.2.1 PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

ADCO GRANISETRON 1 mg/1 ml injection

Each ampoule contains 1 mg granisetron (as hydrochloride) per 1 mL

ADCO GRANISETRON 3 mg/3 ml injection

Each ampoule contains 3 mg granisetron (as hydrochloride) per 3 mL

Sugar free

Read all of this leaflet carefully before you are given ADCO GRANISETRON.

- 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.

What is in this leaflet

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

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1. What ADCO GRANISETRON is and what it is used for

ADCO GRANISETRON is used for the prevention and treatment of nausea and vomiting that may occur after treatment with anticancer medicines (chemotherapy) or with radiation therapy.

ADCO GRANISETRON is also used for the prevention and treatment of postoperative nausea and vomiting.

ADCO GRANISETRON is to be given only by or under the immediate supervision of your doctor.

2. What you need to know before you are given ADCO GRANISETRON

ADCO GRANISETRON should not be administered to you:

- If you are hypersensitive (allergic) to granisetron or any of the other ingredients of ADCO GRANISETRON (listed in section 6)
- In children under the age of 2 years
- If you have an inherited disorder of the heart's electrical activity (known as long QT syndrome).

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

Special care should be taken with ADCO GRANISETRON:

- If you are allergic to any other substances, such as foods, preservatives, or dyes
- If you have ever had any unusual or allergic reaction to ADCO GRANISETRON, dolasetron, or ondansetron
- If you have problems with your bowel such as obstruction or blockage of your small or large intestine. This is because ADCO GRANISETRON may slow down the speed that food is carried to your lower bowel
- Other medical problems – The presence of other medical problems may affect the use of ADCO GRANISETRON. Make sure you tell your doctor if you have any other medical problems
- If you are taking any medicines for your heart
- If you are receiving chemotherapy that might affect your heart
- If you have abnormal electrolyte levels in your body

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- If you have heart problems including abnormal heart rhythm (see section 4).

Children and adolescents

Children

ADCO GRANISETRON has been tested in children 2 years of age and older and, in effective doses, has not been shown to cause different side effects or problems than it does in adults.

Older adults

ADCO GRANISETRON has been tested in a limited number of patients 65 years of age or older and has not been shown to cause different side effects or problems in older people than it does in younger adults.

Other medicines and ADCO GRANISETRON

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

Tell your doctor or other healthcare provider if you are taking any of the following medicines as they may interact with ADCO GRANISETRON:

- Ketoconazole (used to treat fungal infections)
- Medicines used to treat depression and other conditions, called selective serotonin reuptake inhibitors (SSRIs) and selective norepinephrine reuptake inhibitors (SNRIs)
- Medicines used to treat heart problems or medicines that could affect your heart, including a group of medicines called beta-blockers
- Phenobarbital (used to treat fits).

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary.

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Pregnancy, breastfeeding and fertility

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.

Pregnancy

As a precautionary measure, it is preferable to avoid the use of ADCO GRANISETRON during pregnancy.

Breastfeeding

As a precautionary measure, breastfeeding is not advisable during treatment with ADCO GRANISETRON.

Driving and using machines

There have been reports of drowsiness with the use of ADCO GRANISETRON, and this should be taken into account.

It is not always possible to predict to what extent ADCO GRANISETRON 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 ADCO GRANISETRON affects them.

ADCO GRANISETRON contains sodium

ADCO GRANISETRON contains 4,01 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0,2 % of the WHO recommended maximum daily dietary intake of sodium for an adult.

3. How to receive ADCO GRANISETRON

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

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You will not be expected to give yourself ADCO GRANISETRON. It will be given to you by a person who is qualified to do so. ADCO GRANISETRON will be given as slow intravenous injection (into a vein) over at least 30 seconds or as continuous infusion (drip) over a period of 5 minutes. In children, it is given as a continuous infusion (drip) over a period of 5 minutes.

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

Do not stop treatment early.

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

If you receive more ADCO GRANISETRON than you should

Since a healthcare provider will administer ADCO GRANISETRON, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive ADCO GRANISETRON

Since a healthcare provider will administer ADCO GRANISETRON, it is unlikely that the dose will be missed.

4. Possible side effects

ADCO GRANISETRON can have side effects.

Not all side effects reported for ADCO GRANISETRON are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ADCO GRANISETRON, please consult your healthcare provider for advice.

If any of the following happens, stop receiving ADCO GRANISETRON and tell your doctor immediately:

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

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- rash or itching
- fainting.

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

- changes in the way your heart beats, it may be too slow or too fast
- shortness of breath
- involuntary movements that you cannot control, such as twitching, fidgeting, writhing, wriggling, head bobbing or body swaying
- a condition called serotonin syndrome with symptoms such as high blood pressure, fast heart rate, fever, restlessness, trembling or shaking, sweating, dilated pupils, loose stools, fits and muscle damage
- heart problems including abnormal heart rhythm and lack of blood flow to the heart.

These are all serious side effects. May need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache
- constipation
- sleeplessness
- feeling anxious
- restlessness.
- taste disorder
- dizziness
- loss of appetite
- loose stools (diarrhoea)

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- increase in liver enzymes
- fever
- weakness.
- skin rash

Less frequent side effects:

- allergic reactions
- skin rashes
- low blood pressure
- muscle spasm
- abnormal vision
- liver problems
- skin irritation where the injection was given.

Frequency unknown

- high liver enzyme levels

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ADCO GRANISETRON.

For reporting of side effects directly to the Holder of the Certificate of Registration, contact +27 11 635 0134 or email Adcock.aereports@adcock.com.

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5. How to store ADCO GRANISETRON

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light.

Store the ampoules in the carton until required for use.

Do not freeze.

6. Contents of the pack and other information

What ADCO GRANISETRON contains:

The active substance is granisetron.

ADCO GRANISETRON 1 mg/ 1 ml contains 1 mg (as hydrochloride) per 1 mL.

ADCO GRANISETRON 3 mg/ 3 ml contains 3 mg (as hydrochloride) per 3 mL.

The other ingredients are sodium chloride, sodium citrate dihydrate, citric acid anhydrous, water for injections and nitrogen gas.

What ADCO GRANISETRON looks like and contents of the pack

ADCO GRANISETRON 1 mg/1 ml

A clear colourless aqueous solution free from visible particulate matter.

Packed in 1 ml clear, closed, easy breakable glass ampoules for intravenous injection, available in packs of 5 ampoule trays containing 5 ampoules per tray (pack of 25 ampoules).

ADCO GRANISETRON 3 mg/3 ml

A clear colourless aqueous solution free from visible particulate matter.

Packed in 3 ml clear, closed easy breakable glass ampoules for intravenous injection, available in packs of 5 ampoule trays containing 5 ampoules per tray (pack of 25 ampoules).

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Holder of Certificate of Registration

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This leaflet was last revised in

Date of registration: 12 June 2009

Date amended: 14 July 2025

Registration number

ADCO GRANISETRON 1 mg/1 ml: 41/5.7.2/1079

ADCO GRANISETRON 3 mg/3 ml: 41/5.7.2/1080

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