Approved Patient Information Leaflet for
GRANISETRON 1 mg/ml (1 ml) FRESENIUS
GRANISETRON 1 mg/ml (3 ml) FRESENIUS

SCHEDULING STATUS

S4

GRANISETRON 1 mg/ml (1 ml) FRESENIUS

GRANISETRON 1 mg/ml (3 ml) FRESENIUS

Concentrate for solution for injection/infusion

Granisetron

Sugar free.

Read all of this leaflet carefully before you are given GRANISETRON FRESENIUS

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

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

GRANISETRON FRESENIUS is used to prevent and treat nausea (feeling sick) and vomiting (being sick) caused by certain types of treatment such as cancer chemotherapy or radiotherapy.

It can also be used to treat patients who have nausea or vomiting after an operation.

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

You should not be given GRANISETRON FRESENIUS:

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

If you are not sure if the above applies to you, talk to your doctor, nurse or pharmacist before receiving GRANISETRON FRESENIUS.

Warnings and precautions

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

Special care should be taken with GRANISETRON FRESENIUS:

- if you have problems with your bowel such as obstruction or blockage of your small or large intestine. This is because GRANISETRON FRESENIUS may slow down the speed that food is carried to your lower bowel
- if you have heart problems including abnormal heart rhythm
- 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
- if you are allergic to medicines similar to GRANISETRON FRESENIUS, such as dolasetron or ondansetron.

If you are not sure if the above applies to you, talk to your doctor, nurse or pharmacist before receiving GRANISETRON FRESENIUS.

Other medicines and GRANISETRON FRESENIUS

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 GRANISETRON FRESENIUS:

- 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).

Pregnancy, breastfeeding and fertility

Pregnancy

There is limited data on the use of GRANISETRON FRESENIUS in pregnant women. Animal studies do not indicate direct or indirect harmful effects. As a precautionary measure, it is preferable to avoid the use of GRANISETRON FRESENIUS during pregnancy.

Breastfeeding

There is no data on GRANISETRON FRESENIUS in breast milk. As a precautionary measure, breastfeeding is not advisable during treatment with GRANISETRON FRESENIUS.

Fertility

In rats, GRANISETRON FRESENIUS had no harmful effects on reproduction or 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 receiving GRANISETRON FRESENIUS.

Driving and using machines

After receiving GRANISETRON FRESENIUS, you may feel drowsy or sleepy. Depending on your individual reaction, this may compromise your ability to drive or use machines.
It is not always possible to predict to what extent GRANISETRON FRESENIUS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above mentioned activities until they are aware of the measure to which GRANISETRON FRESENIUS affects them.

GRANISETRON FRESENIUS contains sodium

GRANISETRON FRESENIUS contains 3,57 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0,2 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to receive GRANISETRON FRESENIUS

GRANISETRON FRESENIUS is a medicine used in hospitals.
You will not be expected to give yourself GRANISETRON FRESENIUS. It will be given to you by a person who is qualified to do so, as follows:

- In adults, it is given as a slow intravenous injection (into a vein) over at least 30 seconds or as a continuous infusion (drip) over a period of 5 minutes, or by injection into a muscle.
- In children, it is given as a continuous infusion (drip) over a period of 5 minutes.

GRANISETRON FRESENIUS is usually given before the treatment that may make you feel sick. It can also be given after other treatments to stop any sickness that you may have.

Your doctor will decide on the dose and the duration of treatment based on your specific condition and needs.

If you receive more GRANISETRON FRESENIUS than you should

Since a healthcare provider will administer GRANISETRON FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.
If you think you have been given too much of this medicine, tell your doctor, nurse or pharmacist immediately.

If you forget to receive GRANISETRON FRESENIUS

Since a healthcare provider will administer GRANISETRON FRESENIUS, it is unlikely that the dose will be missed.
If you think you have missed an injection, speak to your doctor, nurse or pharmacist.
If you have any further questions on the use of GRANISETRON FRESENIUS, ask your doctor or pharmacist.

4. Possible side effects

GRANISETRON FRESENIUS can have side effects.

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

The most frequent side effects are headache and constipation, which may be temporary.

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

- Shortness of breath, sudden wheeziness, swelling of the face, eyelids or lips, rash or itching affecting your whole body.
- Dizziness or fainting.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache.
- High blood pressure.
- Feeling anxious.
- Restlessness.
- Sleeplessness.
- Drowsiness.
- Dizziness.
- Weakness.
- Loose stools (diarrhoea).
- Constipation.
- Loss of appetite.
- Taste disorder.
- Fever.
- Increase in liver enzymes.

Less frequent side effects:

- Abnormal vision.
- Swelling, including swelling of the face.
- Muscle spasm.
- Uncontrolled movement 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.
- Low blood pressure.
- Liver problems.
- Skin rash.
- Skin irritation where the injection was given.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

Healthcare providers are asked to report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects via the **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 GRANISETRON FRESENIUS.

5. How to store GRANISETRON FRESENIUS

Store all medicines out of reach of children.

Store at or below 25 °C. Do not freeze.

Keep the ampoules in the outer carton to protect from light.

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

Once opened, GRANISETRON FRESENIUS should be used immediately.

GRANISETRON FRESENIUS is for single use only. Discard any unused portion.

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

6. Contents of the pack and other information

What GRANISETRON FRESENIUS contains

The active substance is granisetron.

GRANISETRON 1 mg/ml (1 ml) FRESENIUS contains granisetron hydrochloride equivalent to 1 mg granisetron.

GRANISETRON 1 mg/ml (3 ml) FRESENIUS contains granisetron hydrochloride equivalent to 3 mg granisetron.

The other ingredients are sodium chloride, citric acid monohydrate, sodium hydroxide (for pH-adjustment), hydrochloric acid (for pH-adjustment) and water for injection.

Sugar free.

What GRANISETRON FRESENIUS looks like and contents of the pack:

A clear, colourless solution in 1 ml or 3 ml clear Type I glass ampoules, packed into an outer carton in the following pack sizes:

5 x 1 ml; 10 x 1 ml

5 x 3 ml; 10 x 3 ml

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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GRANISETRON 1 mg/ml (3 ml) FRESENIUS:	44/5.7.2/0672