GRANISETRON KABI

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given GRANISETRON KABI?

GRANISETRON KABI contains the active ingredient granisetron. GRANISETRON KABI is used to prevent nausea (feeling sick) and vomiting. It is especially useful when you need to have medical treatment that may cause you to feel or be sick, for example, chemotherapy, radiotherapy or surgery.

For more information, see Section 1. Why am I being given GRANISETRON KABI? in the full CMI.

2. What should I know before I am given GRANISETRON KABI?

Do not use if you have ever had an allergic reaction to GRANISETRON KABI or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I am given GRANISETRON KABI? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with GRANISETRON KABI and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is GRANISETRON KABI given?

Your doctor will decide how much GRANISETRON KABI you should receive and for how long you should receive it.

More instructions can be found in Section 4. How is GRANISETRON KABI given? in the full CMI.

5. What should I know while receiving GRANISETRON KABI?

Things you should do	 Remind any doctor, dentist or pharmacist who treat you that you are using GRANISETRON KABI. Keep all of your doctor's appointments, so that your progress can be checked.
Things you should not do	Do not take any other medicines whether they require a prescription or not without first telling your doctor.
Driving or using machines	 Be careful before you drive or use any machines or tools until you know how GRANISETRON KABI affects you. GRANISETRON KABI may cause dizziness or drowsiness in some people.
Drinking alcohol	 If you drink alcohol, dizziness or drowsiness may be worse. Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are being given GRANISETRON KABI.
Looking after your medicine	 GRANISETRON KABI is stored by hospital staff in the pharmacy or in the ward This medicine is kept below 25 °C and protected from light.

For more information, see Section 5. What should I know while receiving GRANISETRON KABI? in the full CMI.

6. Are there any side effects?

<u>Less serious side effects</u>: related to <u>nervous system</u> (headache, unusual tiredness or weakness, dizziness or light-headedness, agitation, nervousness, drowsiness, difficulty in sleeping), <u>gastrointestinal</u> (abdominal pain, constipation, diarrhoea) and <u>other</u> (altered taste, fever, skin rash). **Speak to your doctor if you have any of these less serious side effects and they worry you**.

<u>Serious side effects</u>: related to <u>heart</u> (chest pain, changes in your heartbeat, severe dizziness or fainting), <u>nervous system</u> (seizures), <u>serotonin syndrome</u> (fever, sweating, fast heartbeat, agitation or confusion, loss of muscle coordination, possibly loss of consciousness) and <u>allergic reaction</u> (shortness of breath, wheezing or difficulty breathing, swelling of the face/lips/tongue or other parts of the body, rash, itching or hives on the skin). **Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.

GRANISETRON KABI

Active ingredient: granisetron hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using GRANISETRON KABI. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using GRANISETRON KABI.

Where to find information in this leaflet:

- 1. Why am I being given GRANISETRON KABI?
- What should I know before I am given GRANISETRON KABI?
- 3. What if I am taking other medicines?
- 4. How is GRANISETRON KABI given?
- 5. What should I know while receving GRANISETRON KABI?
- 6. Are there any side effects?
- 7. Product details

Why am I being given GRANISETRON KABI?

GRANISETRON KABI contains the active ingredient Granisetron (as granisetron hydrochloride). GRANISETRON KABI belongs to a group of medicines called anti-emetics.

GRANISETRON KABI is used to prevent nausea (feeling sick) and vomiting. It is especially useful when you need to have medical treatment that may cause you to feel or be sick, for example, chemotherapy, radiotherapy or surgery.

Your doctor may have prescribed GRANISETRON KABI for another reason. Ask your doctor if you have any questions about why GRANISETRON KABI has been prescribed for you.

GRANISETRON KABI is available only with a doctor's prescription.

GRANISETRON KABI is not addictive.

2. What should I know before I am given GRANISETRON KABI?

Warnings

Do not use GRANISETRON KABI if:

 you are allergic to granisetron, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face/lips/tongue or other parts of the body, rash, itching or hives on the skin.

Check with your doctor if you:

- have any other medical conditions:
 - a heart condition related to changes in the rhythm or rate of your heartbeat
- take any medicines for any other condition
- have allergies to any other medicines, foods, dyes or preservatives
- have had an allergic reaction with other medicines used to prevent nausea and vomiting, such as ondansetron and tropisetron; you may have an allergic reaction to GRANISETRON KABI as well
- have been given GRANISETRON KABI before, and you became unwell; you may need to be given another medicine instead
- have severe constipation.

If you have not told your doctor about any of the above, tell your doctor before you are given GRANISETRON KABI. During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Your doctor will discuss with you the risks and benefits of receiving GRANISETRON KABI while you are pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Your doctor can discuss with you the risks and benefits of receiving GRANISETRON KABI while you are breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with GRANISETRON KABI and affect how it works.

Medicines that may affect the way GRANISETRON KABI works include:

- Phenobarbitone a medicine used to treat epilepsy. Phenobarbitone may be affected by GRANISETRON KABI or may affect how well GRANISETRON KABI works. You may need different amounts of your medicine, or you may need to take a different medicine.
- Medicines that can affect the serotonin levels in your body; these may include:
 - some antibiotics
 - medicines used to treat depression

- medicines that treat or prevent pain
- some medicines to treat Parkinson's disease
- medicines to treat obesity
- medicines used to treat attention hyperactivity disorder.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect GRANISETRON KABI.

4. How is GRANISETRON KABI given?

How much is given

Your doctor will decide how much GRANISETRON KABI you will receive and for how long you will receive it, this depends on your condition and other factors such as your weight.

How GRANISETRON KABI is given to you

GRANISETRON KABI will only be given to you by a doctor or a nurse.

GRANISETRON KABI will be diluted with a suitable infusion before it is administered to you as a fast or slow single dose injection into a vein (intravenous 'drip').

If you are given too much

Since GRANISETRON KABI is given to you in hospital by a doctor or a nurse, it is very unlikely that you will be given too large a dose.

However, if you think that you have received too much GRANISETRON KABI and you experience severe side effects, tell your doctor immediately.

Symptoms of an overdose may include the side effects listed below in the 'Side effects' section but are usually of a more severe nature. Ask your doctor or pharmacist if you have any concerns.

5. What should I know while receiving GRANISETRON KABI?

Things you should do

Keep all of your doctor's appointments, so that your progress can be checked.

Call your doctor straight away if you:

 become pregnant while being given GRANISETRON KABI

Remind any doctor, dentist or pharmacist who treat you that you are receiving GRANISETRON KABI.

Things you should not do

 Do not take any other medicines whether they require a prescription or not without first telling your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how GRANISETRON KABI affects you.

GRANISETRON KABI may cause dizziness or drowsiness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol, dizziness or drowsiness may be worse. Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are being given GRANISETRON KABI.

Looking after your medicine

- GRANISETRON KABI is stored by hospital staff in the pharmacy or in the ward
- This medicine is kept below 25°C and protected from light.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do	
Nervous system-related:	Speak to your	
Headache	doctor if you	
Unusual tiredness or weakness	have any of these less	
Dizziness or light-headedness	serious side	
Agitation	effects and	
 Nervousness 	they worry you.	
 Drowsiness 		
Difficulty in sleeping		
Gastrointestinal-related:		
Abdominal pain		
 Constipation 		
Diarrhoea		
Other:		
Altered taste		
• Fever		
Skin rash		

Serious side effects

ſ	Serious side effects	What to do
Heart-related:		Call your doctor
	Chest pain	straight away,
	Changes in your heartbeat	or go straight to the
	 Severe dizziness or fainting 	Emergency
Nervous system-related:		Department at

Seizures your nearest hospital if you Serotonin syndrome-related: notice any of Fever these serious **Sweating** side effects. Fast heartbeat Agitation or confusion Loss of muscle coordination Possibly loss of consciousness Allergic reaction-related: Shortness of breath Wheezing or difficulty breathing Swelling of the face/lips/tongue or other parts of the body Rash Itching or hives on the skin

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/safety/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What GRANISETRON KABI contains

Active ingredient	Granisetron hydrochloride
(main ingredient)	
Other ingredients	Citric acid monohydrate
(inactive ingredients)	Sodium chloride
	Hydrochloric acid
	Sodium hydroxide
	Water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What GRANISETRON KABI looks like

GRANISETRON KABI is a clear solution with no visible particles.

GRANISETRON KABI 1 mg/mL (AUST R 159273)

Pack size: 1, 5 and 10 ampoules per carton.

GRANISETRON KABI 3 mg/3 mL (AUST R 159274)

Pack size: 1, 5 and 10 ampoules per carton.

Who distributes GRANISETRON KABI

Fresenius Kabi Australia Pty Limited Level 2, 2 Woodland Way Mount Kuring-gai NSW 2080 Australia

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