GRANISETRON-AFT*



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 using GRANISETRON-AFT?

GRANISETRON-AFT contains the active ingredient granisetron. GRANISETRON-AFT 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 or radiotherapy.

For more information, see Section 1. Why am I using GRANISETRON-AFT? in the full CMI.

2. What should I know before I use GRANISETRON-AFT?

Do not use if you have ever had an allergic reaction to GRANISETRON-AFT 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 use GRANISETRON-AFT? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with GRANISETRON-AFT 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-AFT given?

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

More instructions can be found in Section 4. How do I use GRANISETRON-AFT? in the full CMI.

5. What should I know while receiving GRANISETRON-AFT?

Things you should do	 Remind any doctor, dentist or pharmacist who treat you that you are using GRANISETRON-AFT. 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-AFT affects you. GRANISETRON-AFT 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-AFT.
Looking after your medicine	 GRANISETRON-AFT is stored by hospital staff in the pharmacy of in the ward This medicine is kept below 30 °C and protected from light.

For more information, see Section 5. What should I know while using GRANISETRON-AFT? 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 heart beat, 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 6. Are there any side effects? in the full CMI.



GRANISETRON-AFT

Active ingredient: granisetron hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using GRANISETRON-AFT. 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-AFT.

Where to find information in this leaflet:

- 1. Why am I using GRANISETRON-AFT?
- 2. What should I know before I use GRANISETRON-AFT?
- 3. What if I am taking other medicines?
- 4. How do I use GRANISETRON-AFT?
- 5. What should I know while using GRANISETRON-AFT?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using GRANISETRON-AFT?

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

GRANISETRON-AFT 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 or radiotherapy.

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

GRANISETRON-AFT is available only with a doctor's prescription.

GRANISETRON-AFT is not addictive.

2. What should I know before I use GRANISETRON-AFT?

Warnings

Do not use GRANISETRON-AFT 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 medicine.
- 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 heart beat
- 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-AFT as well
- have been given GRANISETRON-AFT 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-AFT.

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 can discuss with you the risks and benefits of receiving GRANISETRON-AFT 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-AFT 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-AFT and affect how it works.

- Phenobarbitone a medicine used to treat epilepsy
 Phenobarbitone may be affected by GRANISETRONAFT or may affect how well GRANISETRON-AFT 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 affects GRANISETRON-AFT.

4. How is GRANISETRON-AFT given?

How much is given

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

When GRANISETRON-AFT is given

 GRANISETRON-AFT will be administered to you before starting with your chemotherapy or radiotherapy.

How GRANISETRON-AFT is given to you

- GRANISETRON-AFT will only be given to you by a doctor or a nurse
- GRANISETRON-AFT 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 GRANISETRON-AFT

Since GRANISETRON-AFT 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-AFT 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-AFT?

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-AFT

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

Things you should not do

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



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

GRANISETRON-AFT 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-AFT.Looking after your medicine

- GRANISETRON-AFT is stored by hospital staff in the pharmacy of in the ward
- This medicine is kept below 30 °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: Headache Unusual tiredness or weakness Dizziness or light-headedness Nervousness Drowsiness Difficulty in sleeping Gastrointestinal-related: Abdominal pain Constipation Diarrhoea	Speak to your doctor if you have any of these less serious side effects and they worry you.
Other: • Altered taste • Fever • Skin rash	



Serious side effects

Serious side effects	What to do
 Heart-related: Chest pain Changes in your heart beat Severe dizziness or fainting Nervous system-related: Seizures Serotonin syndrome-related: Fever Sweating Fast heart beat Agitation or confusion Loss of muscle coordination Possibly loss of consciousness 	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.
 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/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-AFT contains

Active ingredient	granisetron
(main ingredient)	
Other ingredients	Citric acid monohydrate (to
(inactive ingredients)	adjust pH)
	Sodium chloride
	Sodium citrate dihydrate (to adjust pH)
	Water for injections

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

What GRANISETRON-AFT looks like

GRANISETRON-AFT is a clear, colourless or faintly yellow-brown solution with no visible particles.

GRANISETRON-AFT 1 mg/mL:

1 mL solution is supplied in 1 mL clear glass ampoules.

Pack size: 1 or 5 ampoules per carton.

AUST R 300321

GRANISETRON-AFT 3 mg/3 mL:

3 mL solution is supplied in 5 mL clear glass ampoules.

Pack size: 1 or 5 ampoules per carton.

AUST R 300322

Who distributes GRANISETRON-AFT

AFT Pharmaceuticals Pty Ltd 113 Wicks Road North Ryde NSW 2113 AUSTRALIA

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