

# TROPISETRON-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 Tropisetron-AFT?

Tropisetron-AFT contains the active ingredient Tropisetron hydrochloride. Tropisetron-AFT is used to prevent nausea (feeling sick) and vomiting caused by surgery and by cancer chemotherapy.

For more information, see Section [1. Why am I using Tropisetron-AFT?](#) in the full CMI.

### 2. What should I know before I use Tropisetron-AFT?

Do not use if you have ever had an allergic reaction to Tropisetron-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 Tropisetron-AFT?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Tropisetron-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 do I use Tropisetron-AFT?

- Tropisetron-AFT will only be given by a doctor or nurse.
- For nausea and vomiting caused by surgery, a single 2 mg/2 mL dose is usually given by injection or through an intravenous drip shortly before surgery.
- For nausea and vomiting caused by chemotherapy, a single 5 mg/5 mL dose of Tropisetron-AFT is usually given by injection or through an intravenous drip shortly before chemotherapy is started. This is followed by a 5 mg dose of tropisetron each morning for up to 5 more days, usually taken by mouth.

More instructions can be found in Section [4. How do I use Tropisetron-AFT?](#) in the full CMI.

### 5. What should I know while using Tropisetron-AFT?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Tropisetron-AFT.</li><li>• Before having any surgery that requires general anaesthesia, tell the anaesthetist or the doctor in charge that you are having Tropisetron-AFT.</li><li>• If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given Tropisetron-AFT.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly (if relevant).</li><li>• Do not give this medicine to anyone else, even if their condition seems similar to yours.</li><li>• Do not use it to treat any other complaints unless your doctor tells you to.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• This medicine may cause dizziness or tiredness in some people. If you have any of these symptoms, do not drive or do anything else that could be dangerous.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Tropisetron-AFT will be stored in the pharmacy or on the ward.</li><li>• The solution for injection should be kept in a cool place, where the temperature stays below 30 °C</li></ul>

For more information, see Section [5. What should I know while using Tropisetron-AFT?](#) in the full CMI.

### 6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given Tropisetron-AFT.

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.

# TROPISETRON-AFT

**Active ingredient(s):** *Tropisetron hydrochloride equivalent to Tropisetron 2 mg/2 mg and 5 mg/5 mL, solution for injection and infusion*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Tropisetron-AFT. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. **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 Tropisetron-AFT.**

All medicines have risks and benefits. Your doctor has weighed the risks of you having this medicine against the benefits they expect it will provide.

**If you have any concerns about this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

**Where to find information in this leaflet:**

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

## 1. Why am I using Tropisetron-AFT?

**Tropisetron-AFT contains the active ingredient tropisetron hydrochloride.** Tropisetron-AFT works by stopping the action of a substance in the body called serotonin that is thought to cause the nausea and vomiting.

**Tropisetron-AFT is used to prevent nausea (feeling sick) and vomiting caused by surgery and by cancer chemotherapy.**

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Tropisetron-AFT is only available with a doctor's prescription. It is not addictive.

There is not enough information to recommend its use in children.

## 2. What should I know before I use Tropisetron-AFT?

### Warnings

**Do not use Tropisetron-AFT if:**

- you are allergic to tropisetron hydrochloride, or any of the ingredients listed at the end of this leaflet.
- you have ever had an allergy to similar medicines such as ondansetron, granisetron and dolasetron.
- Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction 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 kidney problems, liver problems, heart problems, high blood pressure that is not controlled  
Your doctor may want to take special precautions if you have any of the above conditions.
- take any medicines for any other condition
- Tell your doctor if you have allergies to any other medicines, foods, dyes or preservatives. Your doctor will want to know if you are prone to allergies.

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. Do not use Tropisetron-AFT if you are pregnant. There is not enough information to recommend its use during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Do not breast-feed while you are using Tropisetron-AFT. It is not known if the active ingredient in Tropisetron-AFT passes into breast milk and could affect your baby.

If you are not sure whether you should be given Tropisetron-AFT, talk to your doctor or nurse.

## 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 Tropisetron-AFT and affect how it works. These include:**

- rifampicin
- phenobarbital
- some medicines for your heart
- any medicine that has caused problems with your heart rhythm since this effect could be worsened

You may need to take different amounts of your medicines or to take different medicines while you are having Tropisetron-AFT. Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/her before you are given this medicine.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Tropisetron-AFT.**

## 4. How do I use Tropisetron-AFT?

### How much to use

Tropisetron-AFT will only be given by a doctor or nurse. The usual dose of Tropisetron-AFT is listed below. However, your doctor will decide what dose and how long you will receive Tropisetron-AFT. This depends on your condition and whether you are using other medicines.

Tropisetron-AFT is given as a slow injection or drip (infusion) directly into a vein.

### For nausea and vomiting caused by surgery

A single 2 mg/2 mL dose is usually given by injection or through an intravenous drip shortly before surgery. If nausea and vomiting happen after surgery, a 2 mg/2 mL dose of Tropisetron-AFT can be given at that time.

### For nausea and vomiting caused by chemotherapy

A single 5 mg/5 mL dose of Tropisetron-AFT is usually given by injection or through an intravenous drip shortly before chemotherapy is started. This is followed by a 5 mg dose of tropisetron each morning for up to 5 more days, usually taken by mouth.

Sometimes a medicine called dexamethasone is given along with Tropisetron-AFT to improve the control of nausea and vomiting.

### If you forget to use Tropisetron-AFT

The injection will be given to you by a nurse or doctor; you will not be giving the injection to yourself.

### If you use too much Tropisetron-AFT

Because Tropisetron-AFT will be given by a doctor or nurse it is unlikely that you will be given too large a dose. Your doctor has information on how to recognize and treat an overdose.

At very high doses, some people may have visual hallucinations (see things that are not there). People with

high blood pressure may have their blood pressure raised even higher.

Ask your doctor or nurse if you have any concerns when you are receiving Tropisetron-AFT. If you think that you were given too much Tropisetron-AFT, you may need urgent medical attention.

### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using Tropisetron-AFT?

### Things you should do

**Before having any surgery that requires general anaesthesia, tell the anaesthetist or the doctor in charge that you are having Tropisetron-AFT.**

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given Tropisetron-AFT.**

### Call your doctor straight away if you:

- do not feel well while you are being given Tropisetron-AFT

Remind any doctor, dentist or pharmacist you visit that you are using Tropisetron-AFT.

### Things you should not do

- Do not give this medicine to anyone else, even if their condition seems similar to yours.
- Do not use it to treat any other complaints unless your doctor tells you to.

### Driving or using machines

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

**Be careful doing jobs that require you to be alert until you know how Tropisetron-AFT affects you.**

This medicine may cause dizziness or tiredness in some people. If you have any of these symptoms, do not drive or do anything else that could be dangerous.

### Drinking alcohol

Tell your doctor if you drink alcohol.

### Looking after your medicine

- Tropisetron-AFT will be stored in the pharmacy or on the ward. The solution for injection should be kept in a cool place, where the temperature stays below 30 °C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. In that case, return it to your pharmacist.

## 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.

Some symptoms may be caused by your medical condition or by other treatments (e.g. surgery or chemotherapy) rather than by this medicine.

Do not be alarmed by these lists of possible side effects. You may not experience any of them.

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
<ul style="list-style-type: none"><li>• headache</li><li>• constipation</li><li>• dizziness or light-headedness</li><li>• tiredness, sleepiness</li><li>• stomach pain</li><li>• diarrhoea</li><li>• loss of appetite</li><li>• hot flushes</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• changes in your heart beat</li><li>• fainting</li><li>• signs of allergy such as rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing</li><li>• tight feeling in the chest</li></ul>	<b>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.</b>

**The above list includes serious side effects which may require medical attention. These side effects are rare.**

**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. Some people may have other side effects not yet known or mentioned in this leaflet. Some side effects will only be found by laboratory testing (e.g. changes in your heart rhythm on an electrocardiogram).

## 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](http://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 Tropisetron-AFT contains

<b>Active ingredient (main ingredient)</b>	2 mg/2 mL or 5 mg/5 mL of the active ingredient tropisetron
<b>Other ingredients (inactive ingredients)</b>	acetic acid sodium acetate sodium chloride water for injections

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

### What Tropisetron-AFT looks like

Tropisetron-AFT ampoules are 2 mL and 5 mL glass ampoules containing a clear, colourless or faintly yellow-brown solution. It is supplied in packs of 1 or 10 ampoules.

Australian Registration Numbers:

2 mg/2 mL: AUST R 189943;

5 mg/5 mL: AUST R 189944

### Who distributes Tropisetron-AFT

AFT Pharmaceuticals Pty. Ltd

113 Wicks Road, North Ryde

NSW 2113

Australia

Email: [customer.service@aftpharm.com](mailto:customer.service@aftpharm.com)

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