

Tropisetron-AFT

Tropisetron hydrochloride equivalent to Tropisetron 2mg/2 mg and 5 mg/5 mL, solution for injection and infusion

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about 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 ensure that you speak to your pharmacist or doctor to obtain the most up-to-date information on 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.

What Tropisetron-AFT is used for

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

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

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.

Before you are given Tropisetron-AFT

When you must not be given it

Do not use Tropisetron-AFT if you have ever had an allergy to:

- tropisetron (the active ingredient in Tropisetron-AFT)
- any of the other ingredients listed at the end of this leaflet
- similar medicines such as ondansetron, granisetron and dolasetron

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.

Do not use Tropisetron-AFT if you are pregnant.

There is not enough information to recommend its use during pregnancy.

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.

Do not use Tropisetron-AFT 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.

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

Before you are given it

Tell your doctor if you have any of the following health problems / 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.

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.

Taking other medicines

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

Some medicines and Tropisetron-AFT may interfere with each other. 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.

How Tropisetron-AFT is given

How much is given

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.

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.

How it is given

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

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

If you take too much (overdose)

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. Ask your doctor or nurse if you have any concerns when you are receiving Tropisetron-AFT.

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.

While you are being given Tropisetron-AFT

Things you must 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.

Tell any other doctor, dentist or pharmacist who treats you that you are being given Tropisetron-AFT.

Things you must 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.

Things to be careful of

Be careful driving, operating machinery or 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.

Side effects

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

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects.

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. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor immediately if you notice any of the following:

- changes in your heart beat
- fainting
- 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
- tight feeling in the chest

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

Tell your doctor if you notice any of the following and they worry you:

- headache
- constipation
- dizziness or light-headedness
- tiredness, sleepiness
- stomach pain
- diarrhoea

- loss of appetite
- hot flushes

Tell your doctor if you notice anything else that is making you feel unwell.

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).

Australian Registration Numbers:

2 mg/2 mL: AUST R 189943

5 mg/5 mL: AUST R 189944

New Zealand:

AFT Pharmaceuticals Ltd

PO Box 33.203

Takapuna

Auckland 0740

This leaflet was prepared on 28 July 2015.

Storage

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.

Product description

What it 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.

Ingredients

Tropisetron-AFT ampoules contain 2 mg/2 mL or 5 mg/5 mL of the active ingredient tropisetron. They also contain:

- acetic acid
- sodium acetate
- sodium chloride
- water for injections

Supplier

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