#### **Consumer Medicine Information**

#### What is in this leaflet

This leaflet answers some common questions about tropisetron.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

# You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

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 MYX is used for

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

The active ingredient in Tropisetron MYX is tropisetron (as hydrochloride). 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 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 have Tropisetron MYX

### When you must not have it

# Do not have tropisetron if you have ever had an allergy to:

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

Some of the 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.

## Do not have tropisetron if you are pregnant.

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

### Do not breast-feed while you are having tropisetron.

It is not known if the active ingredient in tropisetron passes into breast milk and could affect your baby.

Do not have tropisetron 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.

#### Before you start to have 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 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
- serotonergic drugs such as antidepressants

You may need to take different amounts of your medicines or to take different medicines while you are having tropisetron. Your doctor and pharmacist have more information. Tell your doctor if you are taking other serotonergic drugs. Serotonin syndrome (including altered mental status, autonomic instability and neuromuscular abnormalities) has been described following the concomitant use of tropisetron and other serotonergic drugs including selective serotonin reuptake inhibitors (SNRIs).

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

### How Tropisetron MYX is used

### Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

#### If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

## For nausea and vomiting caused by surgery

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

#### If you have too much (Overdose)

Because tropisetron 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 recognise and treat an overdose. Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have had too much tropisetron. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

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 having Tropisetron MYX

#### 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.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are having tropisetron.

Tell any other doctor, dentist or pharmacist who treats you that you are having tropisetron.

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 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 having tropisetron.

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) 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).

#### After having Tropisetron MYX

#### Storage

Store below 25°C.

### Product description

#### What it looks like

Tropisetron MYX 2 mg/2mL solution for injection is supplied in glass ampoules containing a clear, colourless or faintly yellow-brown solution; packs of 5 ampoules.

#### Ingredients

Tropisetron MYX ampoules contain 2 mg of the active ingredient, tropisetron (as hydrochloride). They also contain:

- · acetic acid-glacial
- sodium acetate trihydrate
- · sodium chloride
- · water for injections

#### Sponsor

Mayne Pharma International Pty Ltd ABN 88 007 870 984 1538 Main North Road Salisbury South SA 5106

### Australian Registration Numbers

 $2\ mg/2\ mL$  solution for injection ampoule AUST R 246633

### Date of preparation

This leaflet was prepared in April 2016. MYX is a trade mark of Mayne Pharma International Pty Ltd.