

NAVOBAN®

5mg Capsule

2mg/2ml and 5mg/5ml Injection

tropisetron

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Navoban.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you using it against the benefits they expect it will have for you.

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

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

What Navoban is used for

Navoban 5 mg ampoules and capsules are used in the treatment of cancer to help prevent nausea (feeling sick) and vomiting caused by chemotherapy medicines. Navoban 2 mg ampoules are used to treat nausea and vomiting which may happen after surgery.

The active ingredient in Navoban is tropisetron. It works by stopping the action of a substance in the body called serotonin which is thought to bring about the nausea and vomiting.

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

Your doctor may have prescribed this medicine for another reason.

Navoban is only available with a doctor's prescription. It is not addictive.

Before you use Navoban

When you must not use it

Do not use Navoban if you have an allergy to:

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

You may get hives or an itchy skin rash, flushing of the face, tight feeling in the chest, wheezing or troubled breathing, faintness or other symptoms if you use it.

Do not use Navoban if you are pregnant or intend to become pregnant or you are breast-feeding.

There is not enough information on the use of this medicine in pregnancy. It is not known if Navoban passes into breast milk and could affect your baby.

Do not use Navoban if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Do not use Navoban after the expiry date (EXP) printed on the pack.

If you use it after the expiry date, it may not work or it may make you unwell.

Do not give this medicine to a child.

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

Before you start to use it

Tell your doctor if you have any of these 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 these conditions.

Tell your doctor if you have any allergies to:

- any other medicines
- foods, dyes or preservatives

Your doctor will want to know if you are prone to allergies.

If you have not told your doctor about any of these things, tell them before you use Navoban.

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 Navoban 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 you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using Navoban.

How to use Navoban

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 cancer chemotherapy

Navoban is available as ampoules for injection and as capsules.

Treatment is usually begun in the hospital just before chemotherapy is started. A single 5mg dose of Navoban is usually given by injection or through an intravenous drip.

This is followed by a 5mg dose each morning for up to 5 more days, usually taken by mouth in the form of a capsule.

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

For nausea and vomiting caused by surgery

A single 2mg dose is usually given by injection or through a drip. To prevent nausea and vomiting, the dose is given shortly before surgery. If symptoms happen after surgery, the dose is given at that time.

How to take the capsules

Take Navoban at least one hour before food.

Swallow the capsule with a glass of water or other fluid immediately after getting up in the morning.

If you forget to take the capsule

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the one that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you use too much (Overdose)

Immediately telephone your doctor or National Poisons Information Centre, Dunedin (telephone 0800 POISON or 0800 764 766), or go to the Accident and Emergency Department at your nearest hospital if you think that you or anyone else may have had too much Navoban. 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). In some people with high blood pressure, the blood pressure could rise even higher.

While you are using Navoban

Things you must do

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

Tell any other doctor, dentist or pharmacist that treats you that you are using Navoban.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem to be the same as yours.

Do not use Navoban 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 Navoban affects you. Navoban 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 using Navoban. All medicines 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 side effects may be caused by your medical condition (eg. cancer) or by other treatment (eg. surgery or chemotherapy). Some side effects will only be found by laboratory testing (eg. changes in your heart rhythm on an electrocardiogram).

Do not be alarmed by this list 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 if you notice any of the following and they worry you:

- headache
- constipation
- dizziness
- tiredness, sleepiness
- stomach pain
- diarrhoea
- loss of appetite

The above side effects are usually mild and often go away during treatment.

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

- changes in your heart beat (rare)
- fainting (very rare)
- skin rash or itching, sometimes with flushing of the face (rare)
- tight feeling in the chest (rare)
- wheezing or troubled breathing (rare)

The above side effects could be serious. You may need medical attention.

Tell your doctor if you notice anything else that is making you unwell, even if it is not on this list.

Some people may get other side effects of Navoban.

After using Navoban

Storage

If you are storing the capsules at home:

- Keep the capsules in the original container until it is time to take them.
- Store the capsules in a cool dry place below 30 degrees C.
- Store the Ampoules between 15-30°C
- Do not store Navoban or any other medicine in the bathroom or any other place that is hot or steamy.
- Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines. Navoban will keep well if it is cool and dry.

Keep the medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using Navoban or you find that it has passed the expiry date, ask

your pharmacist what to do with any medicine you have left over.

Product description

What it looks like

Navoban ampoules: 2mL and 5mL glass ampoules containing a clear, colourless or faintly yellow-brown solution; packs containing 1 ampoules.

Navoban capsules: yellow and white capsules marked with NVR and EA5mg in red; packs containing, 5 capsules.

Ingredients

Navoban ampoules: contain 2mg or 5mg of the active ingredient, tropisetron (as tropisetron hydrochloride).

They also contain:

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

The ampoules do not contain any preservative. Once opened, the ampoule should be used immediately and any remainder thrown out.

Navoban capsules: contain 5mg of the active ingredient, tropisetron (as tropisetron hydrochloride).

They also contain:

- silica - colloidal anhydrous
- magnesium stearate
- starch - maize
- lactose
- gelatin
- titanium dioxide
- shellac
- iron oxide red CI77491
- iron oxide yellow CI77492

Sponsor

Navoban is supplied in New Zealand by:

Novartis New Zealand Limited
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