APREPITANT

Aprepitant, 80 mg/capsule and 125 mg/capsule.

What is in this leaflet

Please read this leaflet carefully before you start using APREPITANT.

This leaflet answers some common questions about APREPITANT. 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 taking APREPITANT against the benefits they expect it will have for you.

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

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

What APREPITANT is used for

APREPITANT, in combination with other medicines, is used to prevent nausea (feeling sick) and vomiting associated with cancer chemotherapy.

APREPITANT belongs to a group of medicines called neurokinin 1 (NK1) receptor antagonists. It works by blocking the actions of substances in your brain, called substance P neurokinins, that cause nausea and vomiting.

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

The safety and effectiveness of APREPITANT in children and teenagers under the age of 18 years have not been established.

APREPITANT is not addictive.

Before you use APREPITANT

When you must not use it

Do not use APREPITANT if you have an allergy to aprepitantor any of the ingredients listed at the end of this leaflet.

Do not take APREPITANT if you are taking:

- Cisapride*, used to treat stomach reflux
- pimozide*, used to treat psychotic conditions
- terfenadine and astemizole, antihistamines used for allergic conditions, including hayfever
- St Johns Wort a herb used to treat depression

(* not available in New Zealand)

Taking APREPITANT with these medicines may cause serious or life-threatening reactions.

Do not take APREPITANT if you have a rare hereditary problem of fructose intolerance, glucose-galactose malabsorption, or sucrose-isomaltase insufficiency.

Do not take APREPITANT if you are breast-feeding or plan to breastfeed.

It is not known if APREPITANT passes into breast milk. You and your doctor should discuss whether you should stop breast-feeding or not take APREPITANT.

Do not take APREPITANT if:

- · the packaging is torn or shows signs of tampering
- the expiry date on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start taking APREPITANT, talk to your doctor.

Before you start to use it

Tell your doctor if:

- 1. you have or have had any medical conditions
- 2. you are pregnant or intend to become pregnant

APREPITANT has not been studied in pregnant women. APREPITANT should be used during pregnancy only if clearly needed.

3. you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell the doctor before you take any APREPITANT.

Taking other medicines

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

Some medicines should not be taken with APREPITANT. These include:

- cisapride*, used to treat stomach reflux
- pimozide*, used to treat psychotic conditions
- terfenadine and astemizole, antihistamines used for allergic conditions, including hayfever
- St John's Wort a herb used to treat depression

Taking APREPITANT with these medicines may cause serious or life-threatening reactions.

Some medicines and APREPITANT may interfere with each other. These include:

- warfarin, used to prevent blood clots. Your doctor may order additional blood tests to check the effect of warfarin after you have taken APREPITANT.
- rifampicin, an antibiotic used to treat tuberculosis and other infections
- ketoconazole, used to treat fungal infections
- oral contraceptive pills (also known as the pill). Alternative or "back-up" measures of contraception should be used during treatment with APREPITANT and for one month following the last dose of APREPITANT
- paroxetine, used to treat depression, and obsessive compulsive and panic disorders

^{*} not available in New Zealand

- diltiazem, used to treat angina and high blood pressure
- midazolam, triazolam, or alprazolam, used as sedatives or to treat anxiety or panic disorder
- dexamethasone or methylprednisolone, steroid medicines used for a variety of conditions
- certain cancer chemotherapy agents, including etoposide, vinorelbine, paclitaxel
- tolbutamide, used to treat diabetes
- phenytoin, used to treat epilepsy

These medicines may be affected by APREPITANT or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

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

How to use APREPITANT

How much to take

Take APREPITANT only when prescribed by your doctor.

APREPITANT 3-Day Regimen

Day 1 (day of chemotherapy): APREPITANT 125 mg will be given to you by mouth 1 hour before you start your chemotherapy treatment on Day 1.

Day 2 and Day 3 (the two days after chemotherapy): Take one 80 mg capsule of APREPITANT each morning for the 2 days following your chemotherapy treatment.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

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

How to take it

Swallow each capsule of APREPITANT whole with a glass of water. It does not matter if you take APREPITANT before, with or after food.

How long to take it

APREPITANT is usually taken for 3 days.

If you are not sure how long to take APREPITANT, talk to your doctor.

If you forget to take it

If you forget to take your capsules, contact your doctor for instructions.

While you are using APREPITANT

Things you must do

Women taking oral contraceptive pills for birth control should also use other methods of contraception during treatment with APREPITANT and for one month following the last dose of APREPITANT.

This is because oral contraceptive pills may not work as well when taking APREPITANT.

If you become pregnant while taking APREPITANT, tell your doctor immediately.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking APREPITANT.

Things you must not do

Do not give APREPITANT to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how APREPITANT affects you.

APREPITANT generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many medicines, it may cause certain side effects in some people, including tiredness and dizziness. Make sure you know how you react to APREPITANT before you drive a car or operate machinery.

Things that may be helpful to manage your chemotherapy induced nausea and vomiting

Small, frequent meals or eating a snack before your chemotherapy treatment may help you to tolerate it better.

Talk to your doctor, pharmacist or nurse for more information.

Things that may be helpful to manage your nausea and vomiting caused by your surgery

Talk to your doctor about measures to manage your nausea and vomiting after surgery.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or National Poisons Centre (telephone 0800 POISON or 0800 764 766 or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much APREPITANT.

Do this even if there are no signs of discomfort or poisoning.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using APREPITANT.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. Ask your doctor or pharmacist to answer any questions you may have.

APREPITANT helps most people with nausea and vomiting associated with cancer chemotherapy, but it may have unwanted side effects in a few people.

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

- tiredness
- generally feeling unwell
- muscle weakness
- headache, dizziness
- constipation
- indigestion, heartburn, loss of appetite
- gas from the stomach or bowel, wind
- hiccups/hiccoughs
- vomiting
- disorientation
- hot flushes
- bloating
- pain on urination
- changes to your walking pattern
- acne

Most of these are the more common side effects of APREPITANT. For the most part these have been mild.

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

- slow, fast or irregular heart beat
- · severe upper stomach pain
- symptoms of severe sunburn, such as redness, itching, pain, swelling or blistering
- signs of anaemia such as, being short of breath when exercising, looking pale
- frequent signs of infections such as fever, severe chills, sore throat or mouth ulcers

These may be serious side effects. You may need urgent medical attention. These side effects are rare.

If any of the following happen, tell your doctor immediately or go to accident and emergency at your nearest hospital:

- swelling of the face, lips, mouth, throat or tongue which may cause difficulty in breathing or swallowing
- pinkish, itchy swellings on the skin, also called hives or nettlerash
- severe skin reactions, including the inside of the nose or mouth

These may be serious side effects. If you have them, you may be having a serious allergic reaction to APREPITANT. You may need urgent medical attention. These side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using APREPITANT

Storage

Keep your capsules in the blister pack until it is time to take them. If you take them out of the blister pack, they may not keep well.

Keep APREPITANT in a cool dry place where the temperature stays below 30°C. Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Keep it 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 taking APREPITANT, or the capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

The 80 mg capsule has an opaque white cap and an opaque white body printed with "80 mg" in black ink.

The 125 mg capsule has an opaque pink cap and an opaque white body printed with "125 mg" in black ink.

Ingredients

Active ingredient:

- APREPITANT 80 mg: 80 mg aprepitant per capsule
- APREPITANT 125 mg: 125 mg aprepitant per capsule

Inactive ingredients:

Capsule content

Hydroxypropylcellulose

Sodium laurilsulfate

Sucrose

Cellulose microcrystalline.

Capsule shell

Titanium dioxide

Gelatin

Red iron oxide (125 mg only)

Printing ink:

Shellac

Ammonia solution

Propylene glycol

Potassium hydroxide

Black iron oxide.

APREPITANT does not contain gluten.

Sponsor Details

APREPITANT is supplied in New Zealand by:

Max Health Ltd PO Box 44452 Pt Chevalier, Auckland 1246

Telephone: (09) 815 2664.

Date of Preparation

This leaflet was prepared 12 March 2024.