

Aprepitant APOTEX

aprepitant

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about this medicine. It does not contain all the available information. It does not take the place of talking to your doctor.

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

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

Keep this leaflet with the medicine.

You may need to read it again.

What this medicine is used for

Chemotherapy Induced Nausea and Vomiting

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

Post-Operative Nausea and Vomiting

Aprepitant is used to prevent nausea (feeling sick) and vomiting which can occur after surgery.

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.

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.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- any medicine containing aprepitant.
- any of the ingredients listed at the end of this leaflet.

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 take this medicine 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 John's wort - a herb used to treat depression

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

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- a rare hereditary problem of fructose intolerance, glucose-galactose malabsorption, or sucrose-isomaltase insufficiency

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Aprepitant has not been studied in pregnant women. This medicine should be used during pregnancy

only if clearly needed. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking this medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get 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 this one 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 this medicine and for one month following the last dose of this medicine

- paroxetine, used to treat depression, and obsessive compulsive and panic disorders
- 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 and paclitaxel
- tolbutamide, used to treat diabetes
- phenytoin, used to treat epilepsy

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take this medicine

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 box, ask your doctor for help.

How much to take

Take this medicine only when prescribed by your doctor.

For chemotherapy induced nausea and vomiting

This medicine may be given to you in one of two ways:

1-Day Regimen

- **Day 1 (day of chemotherapy):**
One 165 mg capsule of this medicine will be given to you to take by mouth 1 hour before you

start your chemotherapy treatment on Day 1 only.

OR

3-Day Regimen

- **Day 1 (day of chemotherapy):**

Once 125 mg capsule 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 this medicine each morning for the 2 days following your chemotherapy treatment.

For Post-Operative Nausea and Vomiting

Your doctor will give you one 40 mg capsule of this medicine 3 hours before your surgery.

How to take it

Swallow the capsules whole with a full glass of water.

This medicine can be taken with or without food.

Follow your doctor's instructions about eating or drinking before surgery.

How long to take it

For chemotherapy induced nausea and vomiting, this medicine may be given in one of two ways.

- For the 1-Day regimen, a 165 mg capsule is given only on the day of chemotherapy treatment.
- The 3-Day regimen is usually taken for 3 days.

For post-operative nausea and vomiting, this medicine is given as 1 dose before your surgery.

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

If you forget to take it

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using this medicine

Things you must do

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

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

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

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

Things you must not do

Do not take this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine 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 this medicine affects you.

This medicine 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 this medicine 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 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.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are taking this medicine.

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

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

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

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible 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

The above list includes serious side effects that may require medical attention. Serious 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 nettle rash
- severe skin reactions, including the inside of the nose or mouth

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

Other side effects not listed above may also occur in some people.

Storage and Presentation

Storage

Keep your capsules in the pack until it is time to take them.

If you take the capsules out of the pack, they may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

The 165 mg capsules are presented as opaque hard gelatin capsules with a blue cap and white body, printed with "165mg" on the body. AUST R 309382.

The 125 mg capsules are presented as opaque hard gelatin capsules with a pink cap and white body, printed with "125mg" on the body. AUST R 309363.

The 80 mg capsules are presented as opaque hard gelatin capsules with a white cap and white body, printed with "80mg" on the body. AUST R 309361 and AUST R 309363.

The 40 mg capsules are presented as opaque hard gelatin capsules with a yellow cap and white body, printed with "40mg" on the body. AUST R 309345.

Available in blister packs containing:

1x 165 mg capsules

1x 125mg + 2x 80 mg capsules

2x 80mg capsule

1x 40mg capsule

* Not all pack sizes may be available.

Ingredients

This medicine contains 40 mg, 80 mg, 125 mg or 165 mg of aprepitant as the active ingredient.

This medicine also contains the following:

- sucrose
- microcrystalline cellulose
- hypromellose
- poloxamer

The capsule shell also contains the following:

- gelatin
- titanium dioxide
- sodium lauryl sulfate
- iron oxide yellow (40 mg capsules)
- iron oxide red (125 mg capsules)

- indigo carmine aluminium lake (165 mg capsules)

The capsules are printed with OPACODE monogramming ink S-1-17823 BLACK.

This medicine does not contain lactose, gluten, tartrazine or any other azo dyes.

Supplier

This medicine is supplied in Australia by:

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

This leaflet was last updated in October 2019.