

APO-Exemestane

Contains the active ingredient exemestane

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about exemestane. 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 last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or

- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Exemestane. It contains the active ingredient exemestane.

It is used to:

- Treat breast cancer in women who no longer have their menstrual periods, either naturally due to their age (after menopause) or because they have had their ovaries surgically removed.
- Reduce the risk of recurrence or spreading of the breast cancer. It is also used when the cancer has not responded or has returned after treatment with another medicine or medicines.

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

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

How it works

Exemestane is an aromatase inactivator. It works by significantly reducing the supply of oestrogen to cancer cells.

This stops the growth of those cancer cells which need oestrogen, a natural female sex hormone, to grow.

There is no evidence that this medicine is addictive.

Use in children

This medicine is not recommended for use in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are pregnant.**

Exemestane may affect your developing baby if you take it during pregnancy.

- **You are breastfeeding.**

Exemestane may pass into human breast milk.

- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.
- **You are hypersensitive to, or have had an allergic reaction to, exemestane or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body, rash, itching or hives on the skin; fainting or hayfever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:

- you are still having your monthly period
 - kidney problems
 - liver problems
 - osteoporosis (disease which causes bones to be more brittle and likely to break)
 - a deficiency in vitamin D, your doctor may give you a blood test to determine your vitamin D levels.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant.
 4. You are currently breast-feeding or you plan to breast-feed. Do not take this medicine whilst breast-feeding.
 5. You are planning to have surgery or an anaesthetic.
 6. You are currently receiving or are planning to receive dental treatment.
 7. You are taking or are planning to take any other medicines, This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with exemestane. These include:

- medicines which contain oestrogen, such as hormone replacement therapy (HRT)
- oral contraceptives.

Some health food products for menopausal symptoms contain natural oestrogens.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with exemestane.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

The recommended dosage is one 25 mg tablet taken once daily.

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

When to take it

Take this medicine at the same time each day, preferably after a meal. Taking it at the same time each day will help you remember when to take it.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breast-feeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to

- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you. Exemestane may cause tiredness or dizziness in some people.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking exemestane or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor as soon as possible if you notice any of the following:

- hot flushes
- nausea, vomiting, loss of appetite, indigestion, pain (including stomach ache)
- constipation
- diarrhoea
- tiredness

- dizziness and headache
- increased sweating
- increase in weight
- skin rash
- hair loss

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects and you may need medical attention:

- pain in your muscle or joints
- difficulty sleeping
- depression
- swelling in your legs
- disturbed vision such as blurriness
- bleeding or bruising more easily than normal
- pain and/or numbness of hands, loss of feeling in fingers/thumb
- frequent infections such as fever, severe chills, sore throat or mouth ulcers

- symptoms of gastric ulcer such as blood in stools, black tarry stools or vomiting of blood
- abnormal vaginal bleeding.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- hepatitis, yellowing of the skin or eyes, also called jaundice
- rapid appearance of many pustules and fever (a type of allergic reaction).

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to exemestane, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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
- fainting
- hayfever-like symptoms

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30°C.

Do not store your 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 this 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 or pharmacist tells you to stop taking this medicine or they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO- Exemestane looks like

Exemestane 25 mg tablets are white to off-white, circular, biconvex and are sugar-coated.

Ingredients

Each tablet contains 25 mg of exemestane as the active ingredient.

It also contains the following inactive ingredients:

- microcrystalline cellulose
- crospovidone
- polysorbate 80
- mannitol
- anhydrous colloidal silica
- magnesium stearate

- sucrose
- acacia
- purified talc
- titanium dioxide
- shellac
- beeswax white
- carnauba wax yellow

This medicine is gluten-free, lactose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Exemestane 25 mg tablets (blister pack of 30s): AUST R 177312.

Sponsor

Apotex Pty Ltd

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