

APO-Raloxifene Tablets

Contains the active ingredient raloxifene hydrochloride

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 raloxifene. 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.

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-Raloxifene. It contains the active ingredient raloxifene hydrochloride.

It is used to:

- Prevent and treat osteoporosis in women after menopause. Osteoporosis causes your bones to become thin and fragile - it is especially common in women after menopause. While osteoporosis may have no symptoms at first, it makes your bones more likely to break, especially in your spine, hips and wrists. Osteoporosis may also cause back pain, loss of height and a curved back.
- Fractures may occur during normal, everyday activity, such as lifting, or from minor injury that would not ordinarily fracture normal bone.

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.

There is no evidence that this medicine is addictive.

How it works

Raloxifene belongs to a group of non-hormonal medicines called Selective Estrogen Receptor Modulators (SERMs). When a woman reaches menopause, the level of the female sex hormone, oestrogen, goes down. Raloxifene mimics some of the beneficial effects of oestrogen after menopause.

Before you use this medicine

When you must not use it

Do not use this medicine if:

- **You have had an allergic reaction to raloxifene hydrochloride or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include: 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. If you think you are having an allergic reaction, contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**
- **If you have not been through menopause.**
Raloxifene is only for use by women after menopause and must not be taken by women who could still have a baby.
- **If you are being treated or have been treated for blood clots.**

- **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.**

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:
 - unexplained vaginal bleeding
 - liver disease
 - lactose intolerant
 - APO-Raloxifene contains a small amount of lactose (20 mg) which is unlikely to affect you.
 - menopausal symptoms, such as hot flushes. Raloxifene does not treat hot flushes.
 - high blood fats (triglycerides) caused by oestrogen
 - a stroke or other risk factors for stroke such as a mini-stroke (transient ischaemic attack) or a type of irregular heartbeat called atrial fibrillation
 - breast cancer
 - Raloxifene has not been fully studied in women who have a history of breast cancer.
3. If you are at risk of blood clots.
4. If you are, or know you will be immobilised for some time, e.g., being wheel-chair bound or having to stay in bed while recovering from an operation or illness.
5. If you are on oestrogen or hormone replacement therapy (HRT).
6. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
7. You are currently breastfeeding or you plan to breastfeed.

8. You are planning to have surgery or an anaesthetic.

If you have not told your doctor about any of the above, tell them before you use this medicine.

Before starting and while taking raloxifene you should have breast examinations and mammograms, as directed by your Doctor. Raloxifene does not eliminate the chance of developing breast cancers, you need these examinations to find any breast cancers as early as possible.

Raloxifene is not intended to be taken by men.

Taking other medicines

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

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

- medicines for your heart such as digitalis drugs (e.g. digoxin) or blood thinning drugs such as warfarin. Your doctor may need to adjust the dose of these medicines.
- hormone replacement therapy (HRT) or oestrogens.
- lipid-lowering drugs including cholestyramine.

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

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist carefully and do not use more than the recommended dose.

Their instructions may be different to the information in this leaflet.

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

How much to take

The usual dose of raloxifene is one tablet per day.

How to take it

Raloxifene tablets should be swallowed whole with a glass of water.

When prescribed for the treatment or prevention of osteoporosis, raloxifene should be taken in conjunction with supplementary calcium if daily calcium intake is inadequate.

When to take it

It does not matter what time of day you take your tablet. However, it is best to take it at the same time each day as this will help you remember to take it.

The days of the week are printed on the blister foil to help you take your tablet each day.

You may take raloxifene with or without food.

How long to take it

For maximum benefit, raloxifene is intended for long-term use.

Do not stop taking raloxifene without first talking to your doctor.

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.

If you are not sure what to do, ask your doctor or pharmacist.

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.

In adults, symptoms of an overdose may include leg cramps and dizziness.

In children, symptoms of an overdose may include coordination problems, dizziness, vomiting, rash, diarrhoea, repetitive shaking, and flushing.

While you are taking this medicine

Things you must do

- If you become pregnant while you are using this medicine, tell your doctor.
- Tell any other doctors, dentists and pharmacists who are treating you that you are using this medicine.
- If you are about to be started on any new medicine, tell your doctor or pharmacist that you are using this medicine.
- If you are going to have surgery, inform your doctor and tell the surgeon or anaesthetist that you are using this medicine.
- **Tell your doctor if you are immobilised for some time, e.g., being wheel-chair bound or having to stay in bed while recovering from an operation or illness.**
- **If you are going on a long plane or car trip, you should move about periodically.**

- **Tell your doctor if you have any vaginal bleeding.**

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

This medicine has no known effect on driving or the ability to operate machinery.

Possible side effects

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

Your doctor will decide whether any change in your treatment is needed.

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.

The majority of side effects seen with raloxifene have been mild.

Tell your doctor if you notice any of the following side effects and they worry you:

- hot flushes
- leg cramps
- muscle spasms
- swelling of hands, feet and legs
- flu-like symptoms

These are the more common side effects of raloxifene.

Tell your doctor immediately or go to the Accident and Emergency Department at your nearest hospital if you notice any of the following:

- severe pain or swelling in your legs
- severe stomach pain
- problems with your eyesight
- shortness of breath or pain on breathing

In clinical trials of raloxifene, some women experienced blood clots in the veins (venous thromboembolic events). This occurred in less than 1% of raloxifene patients. This is a serious side effect. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice anything unusual or if you are concerned about any aspect of your health, even if you think the problems are not associated with this medicine and are not referred to in this leaflet.

Clinical trials using raloxifene have shown that:

- Women taking raloxifene have less swelling, tenderness and pain in their breasts than women receiving oestrogen.
- Unlike oestrogen, raloxifene has no effect on the uterus and is unlikely to cause vaginal bleeding or spotting.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Storage and disposal

Storage

Keep your tablets in a cool dry place where the temperature will stay below 25°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-Raloxifene looks like

APO-Raloxifene is a white, oval, biconvex, film-coated tablet, engraved "APO" on one side, "RAL60" on the other side.

Ingredients

Each tablet contains 60 mg of the active ingredient raloxifene hydrochloride.

It also contains the following inactive ingredients:

- lactose
- crospovidone
- magnesium stearate
- silica colloidal anhydrous
- hypromellose
- hydroxypropylcellulose
- macrogol 8000
- titanium dioxide
- purified water

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

APO-Raloxifene tablets are available in:

- Blister packs of 7 and 28 tablets
- Bottles 7, 28, 100 and 500 tablets.

Not all strengths, pack types and/or pack sizes may be available.

Australian Registration Numbers

- APO-Raloxifene 60 mg blister pack:
AUST R 184797
- APO-Raloxifene 60 mg bottle:
AUST R 184794.

Sponsor

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