

RALOXIFENE GH

(raloxifene hydrochloride) film-coated tablets

Consumer Medicine Information

What is in this leaflet

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

All medicines have risks and benefits. Your doctor has more information about this medicine than is contained in this leaflet. Also, your doctor has had the benefit of taking a full and detailed history from you and is in the best position to make an expert judgement to meet your individual needs.

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

Keep this leaflet with this medicine.

You may need to read it again.

What RALOXIFENE GH is used for

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

Raloxifene GH 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 Raloxifene GH has been prescribed for you.

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

Before you take RALOXIFENE GH

Tell your doctor if you have any of the following conditions or if you have ever experienced any of these conditions.

When you must not take it

Do not take Raloxifene GH:

- if you have not been through menopause. Raloxifene GH is only for use by women after menopause and must not be taken by women who could still have a baby;
- if you have had an allergic reaction to Raloxifene GH or any of the ingredients listed at the end of this leaflet; Signs of an allergic reaction may include a skin rash, itching, shortness of breath or swelling of the face, lips or tongue;

- if you are being treated or have been treated for blood clots;
- if the packaging is torn or shows signs of tampering, or if the tablets do not look quite right;
- if the expiry date on the pack has passed. If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure whether you should start taking Raloxifene GH, talk to your doctor or pharmacist.

Before you start to take it

You must tell your doctor:

- if you have any unexplained vaginal bleeding;
- if you are at risk of blood clots;
- if you are, or know you will be immobilised for some time, eg. being wheelchair bound or having to stay in bed while recovering from an operation or illness;
- if you have liver disease;
- if you are intolerant of lactose. Raloxifene GH contains a small amount of lactose in the colourant (about 150 mg) which is unlikely to affect you;
- if you have menopausal symptoms, such as hot flushes. Raloxifene GH does not treat hot flushes;
- if you are breastfeeding;
- if you are on oestrogen or hormone replacement therapy (HRT);
- if you have, or have had, high blood fats (triglycerides) caused by oestrogen;

- if you have previously had a stroke, or if you have ever had other risk factors for stroke such as a mini-stroke (transient ischaemic attack) or a type of irregular heartbeat called atrial fibrillation;
- if you have had breast cancer. Raloxifene GH has not been fully studied in women who have a history of breast cancer.

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

Raloxifene GH is not intended to be taken by men.

Raloxifene GH has no known effect on driving or the ability to use machinery.

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 GH may interfere with each other. These include:

- medicines for your heart such as digitalis drugs (eg. 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 GH.

Tell your doctor about these things before taking Raloxifene GH.

How to take RALOXIFENE GH

Carefully follow all directions given to you by your doctor or pharmacist.

These may differ from the information contained in this leaflet.

How much to take

The usual dose of Raloxifene GH is 1 tablet per day.

How to take it

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

When prescribed for the treatment or prevention of osteoporosis, Raloxifene GH 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 GH with or without food.

How long to take it

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

Do not stop taking Raloxifene GH without first talking to your doctor.

If you forget to take it

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

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

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

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

If you take too much (overdose)

Immediately telephone your doctor or the Australian Poisons Information Centre (13 11 26) or go to the Accident and Emergency Department at your nearest hospital, if you think that you or anyone else has taken too much Raloxifene GH.

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 co-ordination problems, dizziness, vomiting, rash, diarrhoea, repetitive shaking and hot flushes.

While you are taking RALOXIFENE GH

Things you must do

It is important that you remember to take Raloxifene GH daily and at the dose prescribed by your doctor.

Tell all doctors and pharmacists who are treating you that you are taking Raloxifene GH.

While you are taking Raloxifene GH, tell your doctor or pharmacist before you start any new medicine.

If you become pregnant while taking Raloxifene GH, tell your doctor.

Tell your doctor if you are immobilised for some time, eg. being wheelchair 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 stop taking Raloxifene GH without first checking with your doctor.

Do not give Raloxifene GH to anyone else, your doctor has prescribed it specifically for you.

Side effects

Tell your doctor or pharmacist as soon as possible if you experience any undesirable effects or feel unwell while you are taking Raloxifene GH.

Like other medicines, Raloxifene GH may cause some unwanted side effects. These are likely to vary from patient to patient.

The majority of side effects seen with Raloxifene GH 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 GH.

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, some women experienced blood clots in the veins

(venous thromboembolic events). This occurred in less than 1% of 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 have shown that:

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

After taking RALOXIFENE GH

Storage

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

Keep your tablets in a cool, dry place where the temperature stays below 25°C. Do not freeze.

All medicines should be kept where young children cannot reach them.

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

Keep your tablets in their pack until it is time to take them.

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

Do not store Raloxifene GH or any other medicine in the bathroom or near a sink.

Do not leave Raloxifene GH in the car or on window sills.

Heat and dampness can destroy some medicines.

There will be an expiry date (month, year) on your Raloxifene GH pack. The medicine should not

be taken after this date because it may not work as well.

Disposal

If your doctor tells you to stop taking Raloxifene GH, or you find that the tablets have passed their expiry date, please return any leftover tablets to your pharmacist.

Product description

What it looks like

Raloxifene GH tablets are white elliptical film-coated tablets.

In Australia, Raloxifene GH tablets come in blister packs containing 7 (sample pack) and 28 tablets.

Not all pack sizes may be marketed

Ingredients

Active ingredient

Each Raloxifene GH tablet contains 60 mg of raloxifene hydrochloride which is equivalent to 56 mg raloxifene.

Inactive ingredients

- Sodium starch glycolate
- Citric acid monohydrate
- Microcrystalline cellulose
- Calcium hydrogen phosphate
- Poloxamer
- Magnesium stearate
- Opadry White OY-LS-28908 (contains a small amount of lactose monohydrate)

Australian Registration Numbers

Raloxifene GH 60mg: AUST R 199295

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