

Raloxifene GH

Consumer Medicine Information (CMI) Summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Raloxifene GH?

Raloxifene GH contains the active ingredient raloxifene hydrochloride. Raloxifene GH is used to prevent and treat osteoporosis in women after menopause. Raloxifene GH is also used to reduce the risk of invasive breast cancer in women with osteoporosis after menopause and reduce the risk of invasive breast cancer in women at high risk of invasive breast cancer after menopause.

For more information, see Section [1. Why am I using Raloxifene GH?](#) in the full CMI.

2. What should I know before I use Raloxifene GH?

Do not use if you have ever had an allergic reaction to raloxifene hydrochloride or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Raloxifene GH?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Raloxifene GH and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Raloxifene GH?

- The usual dose is 1 tablet per day, which can be taken at any time of the day.

More instructions can be found in Section [4. How do I use Raloxifene GH?](#) in the full CMI.

5. What should I know while using Raloxifene GH?

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| Things you should do | <ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Raloxifene GH.It is important that you remember to take Raloxifene GH daily and at the dose prescribed by your doctor. |
| Things you should not do | <ul style="list-style-type: none">Do not take Raloxifene GH if you have not been through menopause.Do not stop using this medicine without first checking with your doctor.Do not give Raloxifene GH to anyone else, your doctor has prescribed it specifically for you. |
| Driving or using machines | <ul style="list-style-type: none">Raloxifene GH has no known effect on driving or the ability to use machinery. |
| Looking after your medicine | <ul style="list-style-type: none">Keep your tablets in a cool, dry place where the temperature stays below 25°C.Keep your tablets in the blister pack until it is time to take them.Keep your medicine where young children cannot reach it. |

For more information, see Section [5. What should I know while using?](#) in the full CMI.

6. Are there any side effects?

Raloxifene GH may cause hot flushes, leg cramps, muscle spasms, swelling of hands, feet and legs, or flu like symptoms. Serious side effects may be: severe pain or swelling in your legs, severe stomach pain, shortness of breath or pain on breathing, gall stones, blood clots, or problems with your eyesight.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Raloxifene GH

Active ingredient(s): *raloxifene hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Raloxifene GH. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Raloxifene GH.**

Where to find information in this leaflet:

- [1. Why am I using Raloxifene GH?](#)
- [2. What should I know before I use Raloxifene GH?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Raloxifene GH?](#)
- [5. What should I know while using Raloxifene GH?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Raloxifene GH?

Raloxifene GH contains the active ingredient raloxifene hydrochloride. Raloxifene GH belongs to a group of medicines called Selective Estrogen Receptor Modulators (SERMS). When a woman reaches menopause, the level of female sex hormone, estrogen, goes down. Raloxifene GH mimics some of the beneficial effects of estrogen after menopause.

Raloxifene GH is used to prevent and treat osteoporosis in women after menopause. It is also used to reduce the risk of invasive breast cancer in women with osteoporosis after menopause and reduce the risk of invasive breast cancer in women at high risk of invasive breast cancer after menopause.

2. What should I know before I use Raloxifene GH?

Warnings

Do not use Raloxifene GH if you:

- are allergic to raloxifene hydrochloride or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- 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.
- are being treated or have been treated for blood clots.
- are a male. Raloxifene GH is not intended for use in men.

Check with your doctor if you:

- have any unexplained vaginal bleeding.

- are at risk of blood clots.
- 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.
- have liver disease.
- are intolerant to lactose. Raloxifene GH contains a small amount of lactose (150 mg).
- have menopausal symptoms, such as hot flushes. Raloxifene GH does not treat hot flushes.
- are on estrogen or hormone replacement therapy (HRT).
- have or have had high blood fats (triglycerides) caused by estrogen.
- 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 type of irregular heartbeat called atrial fibrillation.
- 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Raloxifene GH is only for use by women after menopause and must not be taken by women who could still have a baby.

Check with your doctor if you are pregnant or intend to become pregnant.

You must tell your doctor if you are breastfeeding or intend to breastfeed.

Impaired liver function

The use of Raloxifene GH is not recommended in this patient population.

Use in men

Raloxifene GH is not intended for use in men.

3. What if I am taking other medicines?

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

Some medicines may interfere with Raloxifene GH and affect how it works. 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.
- (HRT or estrogens.
- lipid-lowering drugs including colestyramine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Raloxifene GH.

4. How do I use Raloxifene GH?

How much to take

- The usual dose of Raloxifene GH is 1 tablet per day.
- For maximum benefit, Raloxifene GH is intended for long-term use.
- Follow the instructions provided and use Raloxifene GH until your doctor tells you to stop.

When to take Raloxifene GH

- 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 remember to take your tablet each day.

How to take Raloxifene GH

- 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.
- You may take Raloxifene GH with or without food.

If you forget to take Raloxifene GH

Raloxifene GH should be taken regularly at the same time each day.

If you miss your dose at the usual time, and it is almost time for your next dose, skip the dose 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 Raloxifene GH as you would normally.

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

If you take too much Raloxifene GH

If you think that you have taken too much Raloxifene GH, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**); or
- contact your doctor; or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Raloxifene GH?

Things you should do

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

Call your doctor straight away if you have:

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

Remind any doctor, dentist or pharmacist you visit that you are using Raloxifene GH.

Things you should not do

- Do not stop using this medicine without first talking to your doctor.
- Do not give Raloxifene GH to anyone else. Your doctor has prescribed it specifically for you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Raloxifene GH affects you.

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

Looking after your medicine

- Store below 25°C.
- Keep your tablets in the blister until it is time to take them.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink; or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

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 have lost some of its strength.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|--|---|
| <p>General Symptoms:</p> <ul style="list-style-type: none"> • Leg cramps. • Swelling of hands, feet and legs. • Flu-like symptoms. • Infection. • Headache. • Fever. • Chest pain. • Breast pain. <p>Cardiovascular:</p> <ul style="list-style-type: none"> • Hot flushes. • Migraine. • Passing out. • Twisted or enlarged veins. <p>Digestive System:</p> <ul style="list-style-type: none"> • Nausea. • Diarrhoea. • Upset stomach. • Vomiting. • Flatulence. <p>Metabolic and Nutritional:</p> <ul style="list-style-type: none"> • Weight gain. <p>Musculoskeletal:</p> <ul style="list-style-type: none"> • Muscle ache. • Muscle spasms. • Joint pain and/or swelling. • Inflammation or irritation of tendon. <p>Nervous System:</p> <ul style="list-style-type: none"> • Depression. • Difficulty sleeping. • Vertigo. • Severe pain anywhere in body. • Reduced sensibility to touch. <p>Respiratory System:</p> <ul style="list-style-type: none"> • Congested nose, runny nose, sneezing and itching. • Sore throat, wheezing and wet cough. | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

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| <ul style="list-style-type: none"> • Hoarseness. <p>Skin and Appendages:</p> <ul style="list-style-type: none"> • Rash. • Sweating. <p>Eye-related:</p> <ul style="list-style-type: none"> • Eye inflammation (including redness, swelling and itching). <p>Metabolic and Nutritional:</p> <ul style="list-style-type: none"> • Weight gain. <p>Urinary System:</p> <ul style="list-style-type: none"> • Inflammation of the vagina. • Urinary tract infection (UTI). • Bladder infection. • Yellowish/greenish discharge from vagina. • Pain white urinary or passing stool. • Uterine disorder. • Vaginal bleeding. | |
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Serious side effects

| Serious side effects | What to do |
|---|--|
| <p>General Symptoms:</p> <ul style="list-style-type: none"> • Severe pain or swelling in your legs. • Severe stomach pain. • Shortness of breath or pain on breathing, fever chills (symptoms of pneumonia). <p>Cardiovascular:</p> <ul style="list-style-type: none"> • Blood clots. <p>Digestive System:</p> <ul style="list-style-type: none"> • Gall stones. <p>Eye-related:</p> <ul style="list-style-type: none"> • Problem with your eyesight. • Pain or redness of the eyes. | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

In clinical trials of raloxifene hydrochloride, 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 or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the

Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Raloxifene GH contains

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| Active ingredient (main ingredient) | raloxifene hydrochloride |
| Other ingredients (inactive ingredients) | Sodium starch glycollate Citric acid monohydrate Microcrystalline cellulose Calcium hydrogen phosphate Poloxamer Magnesium stearate Opadry White OY-LS-28908 (contains a small amount of lactose monohydrate) |
| Potential allergens | Lactose monohydrate |

Do not take this medicine if you are allergic to any of these ingredients.

What Raloxifene GH looks like

Raloxifene GH is a white, elliptical-shaped, film-coated tablet (AUST R 199295).

Who distributes Raloxifene GH

Generic Health Pty Ltd

Suite 2, Level 2

19-23 Prospect Street

Box Hill, VIC, 3128

Australia

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🌐 www.generichealth.com.au

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