

**PACKAGE LEAFLET :
INFORMATION FOR THE USER**

Raloxiep 60 mg Film-coated Tablets
(raloxifene hydrochloride)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Raloxiep 60 mg Film-coated Tablets is and what it is used for
2. What you need to know before you take Raloxiep 60 mg Film-coated Tablets
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1. What Raloxiep 60 mg Film-coated Tablets is and what it is used for

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

Raloxifene is used to treat and prevent osteoporosis in postmenopausal women. Raloxifene reduces the risk of fractures in the spine in women with postmenopausal osteoporosis. A reduction in the risk of hip fractures has not been shown.

Osteoporosis is a disease that causes your bones to become thin and fragile. It is especially common in women after the menopause. Osteoporosis makes you more likely to break bones, especially in your spine, hips and wrists and may cause back pain, loss of height and a curved back.

2. Before you take Raloxiep 60 mg Film-coated Tablets

- Do not take Raloxiep 60 mg Film-coated Tablets
- if you are allergic (hypersensitive) to raloxifene or any of the other ingredients of this medicine (listed in section 6)..
- if you could still have a baby. Raloxifene may harm your unborn child.
- if you are being treated or have been treated for **blood clots** in the legs (deep vein thrombosis), in the lungs (pulmonary embolism) or in the eyes (retinal vein thrombosis).if you have liver disease (like cirrhosis, mild hepatic impairment or cholestatic jaundice).
- if you have any unexplained vaginal bleeding. This must be investigated by your doctor.
- if you have active uterine cancer, as there is insufficient experience of raloxifene use in women with this disease.
- if you have severe **kidney problems**.

Warnings and precautions

- if you are immobilised for some time such as being wheelchair bound, needing to be admitted to a hospital or having to stay in bed while recovering from an operation or an unexpected illness.
- if you receive oral oestrogen therapy.
- if you suffer from breast cancer, as there is insufficient experience of raloxifene use in women with this disease.
- if you have had a cerebrovascular accident (e.g. stroke), or if your doctor has told you that you are at high risk of having one.
- if you have liver disease

Talk to your doctor or pharmacist before taking Raloxiep 60 mg Film-coated Tablets

It is unlikely that raloxifene will cause vaginal bleeding. Therefore any vaginal bleeding while you take raloxifene is unexpected. Contact your doctor for advice.

Raloxifene does not treat postmenopausal symptoms, such as hot flushes.

Raloxifene lowers total cholesterol and LDL ("bad") cholesterol. In general, it does not change the fat levels (triglycerides) or HDL ("good") cholesterol. However, if you have taken oestrogen in the past and had **extreme elevations in triglycerides**, you should **talk to your doctor** before taking raloxifene.

Other medicines and Raloxiep 60 mg Film-coated Tablets

Other medicines may be affected by raloxifene. They, in turn, may affect how well raloxifene works. Raloxifene can interact with:

- **digitalis** medicines for your heart or anticoagulants (substances used to thin your blood) like **warfarin**. Your doctor may need to adjust your dose of these medicines..
- **cholestyramine** (substance mainly used in the treatment of high cholesterol levels), which affects raloxifene by limiting its absorption.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the other medicines listed above or any other medicines.

Taking Raloxiep 60 mg Film-coated Tablets with food and drink

Food and drink do not affect raloxifene.

Pregnancy and breast-feeding

Raloxifene is for use only by postmenopausal women and **must not be taken by women who could still have a baby**. Raloxifene may harm your unborn child.

Do not take raloxifene if you are breast-feeding as it might pass into mother's milk.

Ask your doctor or pharmacist for advice before taking any medicines.

Driving and using machines

Raloxifene has negligible effects on driving or using machinery.

Raloxiep 60 mg Film-coated Tablets contains lactose

This medicine contains **lactose**. If you have been told by your doctor that you have an **intolerance to some sugars**, contact your doctor before taking this medicine.

3. How to take Raloxiep 60 mg Film-coated Tablets

The tablets are for oral use.

The dose is **one tablet a day**. It does not matter what time of day you take your tablet but taking the tablet at the same time each day will help you remember to take it. You may take it with or without food.

Do not break or crush the tablet before taking it. A broken or crushed tablet may taste bad and there is a possibility that you will receive an incorrect dose. If you wish you may take a glass of water with it.

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long you should continue to take raloxifene. The doctor may also advise you to take calcium and vitamin D supplements.

If you take more Raloxiep 60 mg Film-coated Tablets than you should

Tell your doctor or pharmacist. If you take more <Raloxifene 60 mg> than you should you could have leg cramps and dizziness.

If you forget to take Raloxiep 60 mg Film-coated Tablets

If you forget to take your tablet, take the next tablet at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Raloxiep 60 mg Film-coated Tablets

You should talk to your doctor first, before you stop taking raloxifene.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Synthon

Like all medicines, raloxifene can cause side effects, although not everybody gets them. The majority of side effects seen with raloxifene has been mild.

- Very common (affects more than 1 user in 10)
- Hot flushes (vasodilatation)
- Flu syndrome
- Gastrointestinal symptoms such as nausea, vomiting, abdominal pain and stomach upset
- Increased blood pressure
- Common (affects 1 to 10 users in 100)
- Headache including migraine
- Leg cramps
- Swelling of hands, feet and legs (peripheral oedema)
- Gallstones
- Rash
- Mild breast symptoms such as pain, enlargement and tenderness
- Uncommon (affects 1 to 10 users in 1,000)
- Increased risk of blood clots in the legs (deep vein thrombosis)
- Increased risk of blood clots in the lungs (pulmonary embolism)
- Increased risk of blood clots in the eyes (retinal vein thrombosis)
- Skin around the vein is red and painful (superficial vein thrombophlebitis)
- Blood clot in an artery (for example stroke, including an increased risk of dying from stroke)
- Decrease in the number of the platelets in the blood

In rare cases, blood levels of liver enzymes may increase during treatment with raloxifene.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Raloxiep 60 mg Film-coated Tablets

Keep out of the sight and reach of children.
This medicinal product does not require any special storage conditions.

Do not use Raloxiep 60 mg Film-coated Tablets after the expiry date which is stated on the blister and carton after 'EXP'. The first two digits indicate the month and the last four digits indicate the year. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

- What Raloxiep 60 mg Film-coated Tablets contains
- The active substance is raloxifene hydrochloride. Each tablet contains 60 mg of raloxifene hydrochloride, which is equivalent to 56 mg raloxifene.
- The other ingredients in the tablet core are: lactose monohydrate, cellulose microcrystalline (E460), crospovidone (E1202), povidone K30 (E1201), citric acid anhydrous (E330), magnesium stearate (E572).
- The ingredients in the tablet coating are: hypromellose (E464), Macrogol 4000, lactose monohydrate and titanium dioxide (E171).
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What Raloxiep 60 mg Film-coated Tablets looks like and contents of the pack

Raloxiep 60 mg Film-coated Tablets are white oval film-coated tablets, debossed with RX9F on one side and 60 on the other side. Raloxiep 60 mg Film-coated Tablets are packed in blisters containing 7, 10, 14, 20, 21, 28, 30, 40, 50, 70, 84, 100 or 120 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Synthon BV
Microweg 22

6545 CM Nijmegen
The Netherlands

Manufacturer:
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Microweg 22
6545 CM Nijmegen
The Netherlands

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Castelló, 1
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This medicinal product is authorised in the Member States of the EEA under the following names:

NL	Raloxiep 60 mg, filmomhulde tabletten
AT	Raloxifenhydrochlorid Synthon 60 mg Filmtabletten
BE	Raloxiep 60 mg
DE	RaloxNL 60 mg
EL	RaloxNL 60 mg
ES	Hidrocloruro de Raloxifeno Synthon 60 mg, comprimido recubierto con película EFG
FR	Raloxifene hydrochloride Synthon 60 mg, comprimé pelliculé
IE	Raloxiep 60 mg
NO	RaloxNL 60 mg
SE	Ralox 60 mg
UK	Raloxifene hydrochloride 60 mg Tablets

This leaflet was last approved in: <MM/YYYY>