

## Package leaflet: information for the user

# Raloxifene hydrochloride 60mg film-coated tablets

raloxifene hydrochloride

The name of your medicine is Raloxifene hydrochloride which will be referred to as "Raloxifene" throughout this leaflet.

### Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any possible side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet:

1. What Raloxifene is and what it is used for
2. What you need to know before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other information

### 1.What Raloxifene is and what it is used for

This medicine contains the active substance raloxifene hydrochloride.

Raloxifene is used to treat and prevent osteoporosis in post-menopausal women. This medicine reduces the risk of vertebral fractures in women with post-menopausal osteoporosis. A reduction in the risk of hip fractures has not been shown.

### How this medicine works

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

Osteoporosis is a disease that causes your bones to become thin and fragile - this disease is especially common in women after the menopause. Although it may have no symptoms at first, 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.What you need to know before you take Raloxifene

#### Do not take this medicine:

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 are allergic to raloxifene or any of the other ingredients of this medicine (listed in section 6).
- If there is still a possibility that you can get pregnant, this medicine could harm your unborn child.
- If you have liver disease (examples of liver disease include cirrhosis, mild hepatic impairment or cholestatic jaundice).
- If you have severe kidney problems.
- 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.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine:

- If you are immobilised for some time, for example are wheel-chair bound, need to be admitted to a hospital or have to stay in bed while recovering from an operation or an unexpected illness, as your risk of blood clots may increase (deep vein thrombosis, pulmonary embolism or retinal vein thrombosis).
- 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.
- If you are suffering from breast cancer, as there is insufficient experience of raloxifene use in women with this disease.
- If you are receiving oral oestrogen therapy.

It is unlikely that Raloxifene will cause vaginal bleeding, so any vaginal bleeding that occurs while you are taking this medicine is unexpected. You should have this investigated by your doctor.

This medicine does not treat post-menopausal symptoms, such as hot flushes.

This medicine lowers total cholesterol and LDL ('bad') cholesterol. In general, it does not change 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 Raloxifene

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

If you are taking digoxin for your heart or anti-coagulants like warfarin to thin your blood, your doctor may need to adjust your dose of these medicines.

Tell your doctor if you are taking cholestyramine, which is mainly used as a lipid-lowering medicine. You should not take cholestyramine at the same time as raloxifene because raloxifene may not work as well.

#### Pregnancy and breast-feeding

Raloxifene is for use only by post-menopausal women and must not be taken by women who could still have a baby. This medicine could harm your unborn child.

Do not take this medicine if you are breast-feeding as it might be excreted in mother's milk.

#### Driving and using machines

This medicine has no or negligible effects on driving or using machines.

#### Raloxifene 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.

#### Raloxifene contains sodium

This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say essentially "sodium free".

### 3.How to take this medicine

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

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.

The tablets are for oral use.

Swallow the tablet whole. If you wish you may take it with a glass of water. **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.

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

#### If you take more Raloxifene than you should

Tell your doctor or pharmacist. You could have leg cramps and dizziness.

#### If you forget to take this medicine

Take a tablet as soon as you remember and then continue as before. Do not take a double dose to make up for a forgotten dose.

## If you stop taking this medicine

You should talk to your doctor first. It is important that you continue taking Raloxifene for as long as your doctor prescribes the medicine. This medicine can treat or prevent your osteoporosis only if you continue to take the tablets.

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

## 4. Possible side effects

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

All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting the whole body).

If you experience any of the following serious side effects, contact your doctor immediately or go to the nearest hospital accident and emergency department:

### Uncommon side effects (may affect up to 1 in 100 people):

- Swelling, warmth, redness and pain in the legs, these are signs and symptoms associated with blood clots in the legs (deep vein thrombosis).
- Chest pain and shortness of breath, these are signs and symptoms associated with blood clots in the lungs (pulmonary embolism).
- Blurring, loss of vision or patchiness of images, these are signs and symptoms associated with blood clots in the eye (retinal vein thrombosis).
- Pain, whitening of the limbs, weakness, loss of sensation or paralysis, these are signs and symptoms of blood clots in an artery (for example stroke).

### The following side effects have also been reported:

#### Very common (may affect more than 1 in 10 people):

- Hot flushes (vasodilation)
- Flu syndrome
- Gastrointestinal symptoms such as nausea, vomiting, abdominal pain and stomach upset
- Increased blood pressure

#### Common (may affect up to 1 in 10 people):

- 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 (may affect up to 1 in 100 people):

- Skin around the vein is red and painful (superficial vein thrombophlebitis)
- Decrease in the number of platelets in the blood

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

### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme

(website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store).

By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Raloxifene

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer carton and blister after 'EXP'. The expiry date refers to the last day of that month.

Keep the blisters in the outer carton in order to protect from light and moisture. Do not freeze.

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 protect the environment.

## 6. Contents of the pack and other information

### What Raloxifene contains

- The active substance is raloxifene hydrochloride. Each tablet contains 60mg of raloxifene hydrochloride, which is equivalent to 56mg raloxifene.
- The other ingredients are:
  - Tablet core: Sodium starch glycolate, citric acid monohydrate, microcrystalline cellulose, dibasic calcium phosphate, poloxamer 407, magnesium stearate.
  - Tablet coating: Hypromellose, lactose monohydrate, polyethylene glycol, titanium dioxide (E171) and macrogol/PEG 400.

### What this medicine looks like and contents of the pack

Raloxifene are white, elliptical, film-coated tablets. They are packed in blisters. Each carton contains 14, 28, 30, 84, or 90 tablets. Not all pack sizes may be marketed.

## Marketing Authorisation Holder & Manufacturer

### Marketing Authorisation Holder

Aspire Pharma Limited  
Unit 4, Rotherbrook Court  
Bedford Road  
Petersfield  
Hampshire  
GU32 3QG  
United Kingdom

### Manufacturer

Pharmathen SA.  
6 Dervenakion Str., 153 51  
Pallini, Attiki  
Greece

Or

Pharmathen International SA.  
Industrial Park Sapes  
Rodopi Prefecture  
Block No 5  
Rodopi 69300  
Greece

This leaflet was last revised in: 05/2019

1010070-P8.5