PATIENT INFORMATION ON

RALOFIXENE

(Brand name: Evista)

This information sheet has been produced by the Australian Rheumatology Association to help you understand the medicine that has been prescribed for you. It includes important information about:

- **how you should take your medicine**
- **the possible side effects**
- **other precautions you should take while you are taking raloxifene.**

Please read it carefully and discuss it with your doctor.

Important things to remember

- While taking raloxifene you should see your doctor to make sure the treatment is working and to minimise any possible side effects.
- If you are worried about any side effects you should contact your doctor as soon as possible.
- Raloxifene should ***not*** be taken with some other osteoporosis medicines such as bisphosphonates e.g. alendronate (Fosamax, Alendro, Fosamax Plus), risedronate (Actonel, Actonel Combi, Actonel Combi D) and zolendronate (Aclasta), or denosumab (Prolia), strontium (Protos) or teriparatide (Forteo).

For more information about OSTEOPOROSIS see the Osteoporosis Australia website http://www.osteoporosis.org.au/ or phone Osteoporosis Australia on 1800 242 141.

What is raloxifene?

Raloxifene (brand name Evista) is a medicine used to treat osteoporosis. It is prescribed only for women as it works on female hormones.

Osteoporosis is a common disease which causes bones to become fragile and brittle so that they break (fracture) more easily even as a result of normal activity (as distinct from a fall). Fractures are painful and restrict a person's ability to carry out their normal daily tasks.

Once you have a fracture the risk of another is high. Raloxifene is prescribed for women who have already had a fracture in order to reduce the risk of further fractures.

How does it work?

Bone is constantly changing with old bone breaking down and new bone being formed to take its place. This usually happens in a balanced way. If the cycle becomes unbalanced bone breaks down faster than it is replaced. This leads to osteoporosis.

Raloxifene is a medicine that slows or stops the bone breaking down. As a result bone strength increases and the risk of fracture is reduced.

What benefit can you expect from your treatment?

Since osteoporosis doesn't usually have any symptoms such as pain (until a fracture occurs) you will not 'feel' any immediate benefit from your treatment with raloxifene.

You may be asked to have tests to check the effect of treatment on your bones. For example a bone mineral density test is usually done after one to two years of treatment. This is a type of X-ray that involves a very small amount of radiation.

Tests of urine or blood are sometimes used to measure the effects of treatment on bone formation and breakdown.

How is raloxifene taken?

What is the dosage and when should it be taken?

Raloxifene is taken by mouth and comes in 60mg tablets. The dose is one tablet every day. It can be taken with or without food and at any time.

To help you remember to take raloxifene take it at about the same time each day.

If you miss a dose take it as soon as you remember. However, if it is almost time for your next dose skip the missed dose and take only your next regularly scheduled dose. Do not take two doses at the same time.

Can other medicines be taken with raloxifene?

It is safe to take most other medicines when you are taking raloxifene. However, it should ***not*** be taken with some other osteoporosis medicines (refer *Precautions*, page 3).

Your doctor will usually recommend that you take calcium and vitamin D as additional treatment for osteoporosis.

How long is the treatment continued?

For osteoporosis, treatment with raloxifene is usually given for a number of years. Your doctor will review your progress each year. Once you have had one fracture your chance of having another one is high so it is important to keep taking the medicine as long as it is effective and as long as no serious side effects occur.

Are there any side effects?

Most people who take raloxifene do not experience side effects. Tell your doctor if you are concerned about possible side effects.

A reduction in dose or change to another medicine may minimise the side effects so that you can continue to have treatment for your bones.

Most common possible side effects

Most common side effects include:

- *hot flushes* – these are more common during the first 6 months of treatment
- *dryness in the vagina*
- *leg cramps*
- *swelling* of the hands, feet, ankles, or lower legs.

Less common or rare possible side effects

Less common side effects include:

- *Blood clot* in a vein is rare. Contact your doctor immediately if you experience pain or swelling in your legs or a sudden shortness of breath. Because of this risk your doctor may advise you to stop raloxifene around the time of an operation or before a long-haul flight.
- There are a number of other uncommon side effects and precautions that are described in the leaflet that comes with the medicine. You should read the leaflet and talk to your doctor if you have any concerns.

What precautions are necessary?

Blood tests

- Monitoring blood tests are not usually required for people taking raloxifene, although in certain situations these may be needed.

Liver disease

- Raloxifene may not be recommended if you have severe liver disease.

Use with other medicines

- You should tell your doctor (including your general practitioner, rheumatologist and others) about all medicines you are taking or plan to take. This includes over the counter or herbal/naturopathic medicines. You should also mention your treatment when you see other health professionals.
- Raloxifene should ***not*** be taken with some other osteoporosis medicines such as

bisphosphonates e.g. alendronate (Fosamax, Alendro, Fosamax Plus), risedronate (Actonel, Actonel Combi, Actonel Combi D) and zolendronate (Aclasta), or denosumab (Prolia), strontium (Protos) or teriparatide (Forteo).

- Aspirin can be used safely with raloxifene in the low doses taken for prevention of heart attack and stroke.
- You should not take oral oestrogen therapy (i.e. tablets) if you are on raloxifene. Topical oestrogen treatment such as patches or creams may be used safely.
- You should not take cholestyramine or colestipol while you are taking raloxifene.

Use in pregnancy and breastfeeding

- Raloxifene is only recommended for post-menopausal women. It is not recommended to be taken during pregnancy or during breastfeeding.
- More detailed information is available at https://rheumatology.org.au/gps/documents/ARAPregnancyPrescribingGuidanceupdateApr19.pdf

Other considerations

- Raloxifene has not been shown to cause spotting or menstrual-like bleeding or increase the risk of cancer of the lining of the uterus. However, tell your doctor if you develop vaginal bleeding or spotting. Your doctor will need to examine you or order tests to find the cause of the bleeding.
- Raloxifene has been shown to reduce the chance that you will develop invasive breast cancer. However, you should have a breast examination and mammogram before you start taking raloxifene and during your treatment with the medicine. Call your doctor if you notice tenderness, enlargement, lumps, or any other changes in your breasts.

How to store raloxifene

- Store raloxifene in a cool, dry place, away from direct heat and light.
- Keep all medicines out of reach of children.

Questions?

If you have any questions or concerns write them down and discuss them with your doctor.

Your doctor's contact details

If you are taking raloxifene you should see your doctor regularly to make sure the treatment is working and to minimise any possible side effects.