FIXTA 60

Raloxifene hydrochloride

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 FIXTA is used for

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

FIXTA 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.

Your doctor may have prescribed FIXTA for another reason.

Ask your doctor if you have any questions about why FIXTA has been prescribed for you.

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

Before you take FIXTA

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 FIXTA

Do not take FIXTA:

- if you have not been through menopause. FIXTA 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 FIXTA or any of the ingredients listed at the end of this leaflet (see 'Product Description'). 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 FIXTA, talk to your doctor or pharmacist.

Before you start taking FIXTA

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, e.g., being wheel-chair bound or having to stay in bed while recovering from an operation or illness.
- if you have liver disease.
- if you have menopausal symptoms, such as hot flushes. FIXTA 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. FIXTA has not been fully studied in women who have a history of breast cancer.

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

FIXTA is not intended to be taken by men. FIXTA 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 FIXTA may interfere with each other. These include:

- medicines for your heart such as digitalis drugs (e.g. 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 FIXTA.

Tell your doctor about these things before taking FIXTA.

How to take FIXTA

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 FIXTA is one tablet per day.

How to take it

FIXTA tablets should be swallowed whole with a glass of water.

When prescribed for the treatment or prevention of osteoporosis, FIXTA 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.

You may take FIXTA with or without food.

How long do I take it

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

Do not stop taking FIXTA 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

Immediately telephone your doctor or the Australian Poisons Information Centre (13 11 26), or the New Zealand National Poisons Information Centre (0800 POISON or 0800 764 766), or go to the Accident and Emergency Department at your nearest hospital, if you think that you or anyone else has taken too much FIXTA.
Do this even if there are no signs of discomfort or poisoning.

In adults, symptoms of an overdose may include leg cramps and dizziness.

In children, symptoms of an overdose may include coordination problems, dizziness, vomiting, rash, diarrhoea, repetitive shaking, and flushing.

While you are taking FIXTA

Things you must do

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

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

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

If you become pregnant while taking FIXTA, tell your doctor.

Tell your doctor if you are immobilised for some time, e.g., being wheel-chair 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 FIXTA without first checking with your doctor.

Do not give FIXTA 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 effect or feel unwell while you are taking FIXTA.

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

The majority of side effects seen with FIXTA 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 FIXTA.

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 of raloxifene, some women experienced blood clots in the veins (venous thromboembolic events). This occurred in less than 1% of raloxifene 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 using raloxifene have shown that:

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

After using FIXTA

Storage

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

Keep your tablets in a cool, dry place where the temperature stays below 25 degrees C.

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

There will be an expiry date (month, year) on your FIXTA pack.

The medicine should not be taken after this date because it may have lost some of its strength.

Disposal

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

Product Description

What it looks like

FIXTA 60 (60 mg raloxifene as hydrochloride) are presented in pack size of 7 & 28 tablets in blister and 30 & 100 tablets in bottle pack.

FIXTA 60
White to off-white, elliptical, film-coated tablets debossed with 'X' on one side and '57' on other side.

Ingredients

Active ingredient

Raloxifene Hydrochloride

Inactive ingredients

- microcrystalline cellulose
- Povidone
- polysorbate 80
- crospovidone
- magnesium stearate
- hypromellose
- macrogol 400
- citric acid monohydrate
- titanium dioxide

Name and Address of the Sponsor

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