

PrFEMARA*

(letrozole)

2.5 mg Tablets

Information for the Consumer

Before using **PrFEMARA*** (letrozole), please read this leaflet carefully since it contains important information about this medicine. If you have further questions or further concerns, ask your doctor or pharmacist.

What is FEMARA*?

FEMARA* tablets contain the active substance letrozole. FEMARA* also contains the following non-medicinal ingredients needed to make the tablets: cellulose compounds (microcrystalline cellulose and methylhydroxypropylcellulose), corn starch, iron oxide, lactose, magnesium stearate, polyethylene glycol, sodium starch glycolate, silicon dioxide, talc and titanium dioxide. If you are on a special diet, or if you are allergic to any substance, ask your doctor or pharmacist whether any of these ingredients may cause a problem.

What does FEMARA* do?

FEMARA* is an aromatase inhibitor used to treat breast cancer in women who have passed menopause. It acts by reducing the production of the sex hormone, estrogen, in your body. Estrogens may stimulate the growth of certain types of breast cancer.

When it should not be used:

Do not take FEMARA*:

- if you have ever had an unusual or allergic reaction to letrozole or any other ingredient in FEMARA*
- if you still have menstrual periods

- if you are pregnant or breast feeding, as FEMARA* may harm your baby.

If the answer to any of these questions is YES, FEMARA* is not suitable for you.

FEMARA* should not be used in children or adolescents (under 18 years of age).

People aged 65 years and over can use FEMARA* at the same dose as other adults.

Before using FEMARA* please inform your doctor if you:

- have a serious kidney or serious liver disease
- are taking hormone replacement therapy
- are taking other medication to treat your cancer
- have a personal/family history of osteoporosis or have ever diagnosed with low bone density or have a recent history of fractures (in order for your doctor to assess your bone health on a regular basis).
- have a family or personal history of high blood cholesterol or lipid levels.
- have or have had cardiovascular or heart disease including any of the following: heart attack, stroke or uncontrolled blood pressure.
- have an intolerance to milk sugar (lactose).

Warnings and Precautions

FEMARA* should not be used in children or adolescents (under 18 years of age).

FEMARA* is not recommended in pre-menopausal women as safety and efficacy have not be established in this group of patients.

You should **not** use FEMARA* if you may become pregnant, are pregnant and/or breastfeeding. There is a potential risk of harm to you and the fetus, including risk of fetal malformations. If you have the potential to become pregnant (this includes women who are perimenopausal or who recently became postmenopause), you should discuss with your doctor about the need for adequate contraception.

If there is exposure to FEMARA* during pregnancy, you should contact your doctor immediately to discuss the potential of harm to your fetus and potential risk for loss of the pregnancy.

FEMARA* reduces blood estrogen levels which may cause a reduction in bone mineral density and a potential increase in bone loss (osteoporosis) and/or bone fractures.

The use of aromatase inhibitors, including FEMARA*, may increase the risk of cardiovascular events compared to tamoxifen, such as heart attacks and stroke. Women at risk of heart disease should be carefully monitored by their doctor.

The use of aromatase inhibitors, including FEMARA*, may increase lipid levels. Your doctor should continue routine checking of your lipid and cholesterol levels on a regular basis.

Driving a vehicle or using machinery

FEMARA* tablets are unlikely to affect your ability to drive a car or to use machinery. However, some patients may occasionally feel tired, dizzy, sleepy or experience visual disorders. If this happens, you should not drive or operate any tools or machinery until you feel normal again.

What dosage forms FEMARA* comes in and how it is supplied

FEMARA* (letrozole) is supplied as 2.5 mg film-coated tablets. The film-coated tablets are dark-yellow and round with beveled edges. They are marked with “FV” on one side and “CG” on the other.

FEMARA* is supplied in blister packs containing 30 tablets.

How to take FEMARA*

The usual dosage is one tablet of FEMARA* to be taken once daily. The tablet should be swallowed whole with a small glass of water. You can take FEMARA* with or without food. It is best to take FEMARA* at about the same time every day.

What if you miss a dose?

If you forget to take a dose of FEMARA*, don't worry, take the missed dose as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and

go back to your regular dosage schedule. Do not take a double doses to make up for the one you missed.

Overdose

If overdosage is known or suspected, contact your doctor or the nearest poison control center for advice immediately. Show the pack of tablets. Medical treatment may be necessary.

Medicines or substances that may interfere with the action of FEMARA*

Please tell your doctor or pharmacist if you have recently taken any other prescription or over-the-counter medicines, vitamins or natural health products during your treatment with FEMARA*.

What Side Effects can FEMARA* have?

Like all medicines, FEMARA* can have some side effects, although not everyone gets them. Most side effects that have been observed were mild to moderate. Check with your doctor if the unwanted effects do not go away during treatment or become bothersome.

Some side effects, such as hot flushes, hair loss or vaginal bleeding may be due to lack of estrogen in your body.

If you have to take FEMARA* over a long period of time, there may be a decrease in your bone mineral density or a potential increase in osteoporosis or bone fractures. FEMARA* may potentially impact your cholesterol levels. Your doctor should continue routine checking of your cholesterol levels on a regular basis. Talk to your doctor if you have a personal or family history of high cholesterol or osteoporosis or a recent history of fractures.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Some side effects can be serious.

- weakness or paralysis of limbs or face, difficulty speaking (signs of stroke),
- crushing chest pain or sudden arm or leg (foot) pain (signs of heart disorder such as heart attack),
- swelling and redness along a vein which is extremely tender and possibly painful when touched (signs of inflammation of a vein, e.g. thrombophlebitis),
- difficulty breathing, chest pain, fainting rapid heart rate, bluish skin discoloration (signs of blood clot formation in the lung, e.g. pulmonary embolism),
- swelling of arms, hands, feet, ankles or other parts of the body (signs of oedema),
- severe fever, chills or mouth ulcers due to infections (signs of low level of white blood cells),
- blurred vision (sign of cataract),
- persistent sad mood (depression).

If you experience any of these, stop FEMARA* and consult your doctor immediately.

Other side effects:

- hot flushes,
- pain in bones and joints,
- headache,
- dizziness,
- gastrointestinal disorders (such as, nausea, vomiting, indigestion, constipation, diarrhea),
- depression,
- hair loss,
- fatigue,
- increased sweating,
- vaginal disorders (such as bleeding, discharge or dryness),
- joint stiffness (arthritis),
- breast pain.

Side effects experienced post-market

- rash,
- generally feeling unwell,
- pain in muscles,
- bone loss,
- bone fractures,
- weight increase,
- nervous disorders (such as anxiety, nervousness, irritability, drowsiness, memory problems, insomnia),
- disturbed physical sensitivity (dysaesthesia),
- eye irritation,
- palpitations, rapid heart rate, raised blood pressure (hypertension),
- dry skin, itchy rash (urticaria),
- abdominal pain,
- fever,
- thirst, taste disorder, dry mouth,
- dryness of mucous membranes,
- weight decrease,
- urinary tract infection, increased frequency of urination,
- cough,
- high level of cholesterol (hypercholesterolemia),
- abnormal liver function test results (blood test disorders).

This is not a complete list of side effects. For any unexpected effects while taking FEMARA*, contact your doctor or pharmacist.

Expiry date

Do not take FEMARA* after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of the month. Remember to take any unused medication back to your pharmacist.

How to store FEMARA*

Store your tablets in a dry place at room temperature 15 to 30°C. Avoid places where the temperature may rise above 30°C. Protect from moisture.

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

Do not use any pack that is damaged or shows signs of tampering.

Always remember

This medicine has been prescribed to you for your current medical condition only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours. Do not use it yourself for other problems.

More Information

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.novartis.ca>

or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc, at:
1-800-363-8883

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Last revised: April 23, 2007