**CONSUMER INFORMATION**

**PrFEMARA®**
**(letrozole tablets)**

**This leaflet is part III of a three-part "Product Monograph" published when FEMARA® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about FEMARA. Contact your doctor or pharmacist if you have any questions about the drug.**

## ABOUT THIS MEDICATION

**What FEMARA is used for:**

- The adjuvant treatment of postmenopausal women with hormone receptor-positive invasive early breast cancer;
- The extended adjuvant treatment of hormone receptor positive invasive early breast cancer in postmenopausal women who have received approximately 5 years of prior standard adjuvant tamoxifen therapy;
- The first-line therapy in postmenopausal women with advanced breast cancer; and
- The hormonal treatment of advanced metastatic breast cancer after relapse or disease progression in women with natural or artificially-induced postmenopausal endocrine status, who have previously been treated with antiestrogens.

**What does FEMARA do:**

Estrogen is a normally occurring female sex hormone that stimulates normal breast tissue and the growth of some types of breast cancer. FEMARA is an aromatase inhibitor which acts by binding to aromatase, a substance needed to make estrogen. As a result, the production of estrogen and the growth of breast cancer are reduced.

***What is adjuvant therapy:***
Adjuvant therapy in breast cancer refers to treatment following breast surgery (the primary or initial treatment) in order to reduce the risk of recurrence. The purpose of adjuvant therapy with FEMARA is to treat hormone receptor-positive early breast cancer, after surgery, in postmenopausal women to reduce the risk of recurrence.

***What is extended adjuvant therapy:***
The purpose of extended adjuvant therapy with FEMARA is to treat hormone receptor-positive early breast cancer in postmenopausal women who have received approximately 5 years of prior standard adjuvant tamoxifen therapy in order to prevent recurrence. Treating breast cancer with FEMARA beyond the standard 5 years of hormone therapy is called "extended adjuvant therapy".

**When it should not be used:**

FEMARA should not be used in children and adolescents under 18 years of age.

FEMARA should not be used in hormone-receptor negative disease.

***Do not take FEMARA if you:***
- have ever had an unusual or allergic reaction to letrozole or any other ingredient in FEMARA;
- still have menstrual periods;
- are pregnant or breast-feeding, as FEMARA may harm your baby.

**What the medicinal ingredient is:**

Letrozole

**What the nonmedicinal ingredients are:**

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.

**What dosage forms it comes in:**

FEMARA (letrozole) 2.5 mg tablets

FEMARA is supplied as film-coated tablets. The film-coated tablets are dark-yellow and round with bevelled edges. They are marked with "FV" on one side and "CG" on the other.

FEMARA is supplied in blister packs containing 30 tablets.

## WARNINGS AND PRECAUTIONS

**Serious Warnings and Precautions**

FEMARA should be used under the supervision of a doctor experienced in the use of anti-cancer drugs.

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.

You should **not** use FEMARA if you may become pregnant, or are pregnant. There is a potential risk of harm to you and the fetus. There are reports of spontaneous abortions and abnormalities in babies born to mothers who took FEMARA during pregnancy. If you have the potential to become pregnant (this includes women who are perimenopausal or who recently became postmenopausal), you should discuss with your doctor about the need for effective contraception. Use effective birth control during treatment and for at least 20 days after stopping

FEMARA. Ask your doctor about options of for effective birth control.

You should **not** use FEMARA if you are breastfeeding. There is a potential risk of harm to breastfed babies.

Femara may reduce fertility in males.

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 should not be used in children and adolescents under 18 years of age.

Before you take FEMARA:

*Tell 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 or family history of osteoporosis or have ever been 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 personal or family history of high blood cholesterol or lipid levels. FEMARA may increase lipid levels;
- have or have had cardiovascular or heart disease including any of the following: heart attack, stroke or uncontrolled blood pressure. FEMARA may increase the risk of cardiovascular or heart diseases;
- have an intolerance to milk sugar (lactose);
- have pain in bones, or joints or muscles.

Your level of hormones may be checked by your doctor before you take FEMARA and regularly during the first 6 months of treatment to confirm your menopausal status (cessation of periods).

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.

## INTERACTIONS WITH THIS MEDICATION

Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or over-the-counter medicines, vitamins or natural health products during your treatment with FEMARA. This includes in particular:

- Tamoxifen.
- Other anti-estrogens or estrogen-containing therapies.

These substances may diminish the action of FEMARA.

## PROPER USE OF THIS MEDICATION

**Usual dose:**

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.

**Overdose:**

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

**Missed 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 (e.g. within 2 or 3 hours), skip the missed dose and go back to your regular dosage schedule. Do not take a double dose to make up for the one that you missed.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with all medicines, patients taking FEMARA may experience side effects. Most side effects that have been observed were mild to moderate and will generally disappear after a few days to a few weeks of treatment. 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 the lack of estrogen in your body.

**Very common side effects (*they affect more than 10 in every 100 patients*)**

- increased level of cholesterol (hypercholesterolemia)
- hot flushes
- increased sweating
- night sweats
- fatigue (including weakness and malaise (generally feeling unwell))
- pain in bones and joints (arthralgia).

**Common side effects (*they affect between 1 to 10 in every 100 patients*)**

- headache
- rash
- dizziness, vertigo
- gastrointestinal disorders (such as, nausea, vomiting, indigestion, constipation, diarrhea)
- increase in or loss of appetite
- increased blood sugar (hyperglycaemia)
- urinary incontinence
- pain in muscles
- bone loss (osteoporosis)
- bone fractures
- depression
- weight increase
- anxiety
- insomnia
- hair loss

- vaginal bleeding
- dry skin
- raised blood pressure (hypertension)
- abdominal pain.
- Back pain
- Fall
- Palpitations (rapid heart rate)
- Joint stiffness (arthritis)
- Chest pain

**Uncommon side effects (*they affect between 1 to 10 in every 1000 patients*)**

- nervous disorders (such as nervousness, irritability, drowsiness)
- pain or burning sensation in the hands or wrists (carpal tunnel syndrome)
- reduced sense of touch (dysaesthesia)
- eye irritation
- itchy rash (urticaria), rapid swelling of face, lips, tongue, throat (angioedema)
- severe allergic reaction (anaphylactic reaction)
- vaginal disorders (such as discharge or dryness)
- breast pain
- fever
- thirst, taste disorder, dry mouth
- dryness of mucous membranes
- weight decrease
- urinary tract infection, increased frequency of urination
- cough
- abnormal liver function test results (blood test disorders)
- Increased bilirubin level (dark coloured urine)
- Jaundice (yellowish eyes and/or skin).

**Side effects with frequency not known**

- trigger finger, a condition in which your finger or thumb catches in a bent position.

If any of these affects you severely, **tell your doctor**.

If you notice any other side effects not listed in this leaflet, please tell your doctor or pharmacist.

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

| Symptom / effect | Talk with your doctor or pharmacist | | Stop taking drug and call your doctor or pharmacist |
|---|---|---|---|
| | Only if severe | In all cases | |
| **Common** | | | |
| -Pain in the muscles, bones and joints; | √ | | |
| -Joint stiffness; | √ | | |
| -Persistent sad mood (i.e. depression). | | √ | |

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

| Symptom / effect | Talk with your doctor or pharmacist | | Stop taking drug and call your doctor or pharmacist |
|---|---|---|---|
| | Only if severe | In all cases | |
| **Uncommon** | | | |
| - Tightness or feeling of heaviness in the chest or pain radiating from your chest to your arms or shoulders, neck, teeth or jaw, abdomen or back (signs of angina pectoris or heart attack); | | | √ |
| umbness or weakness in arm or leg or any part of the body, loss of coordination, vision changes, sudden headache, nausea, loss of coordination, difficulty in speaking or breathing (signs of brain disease e.g. stroke); | | | √ |
| - Swelling and redness along a vein which is extremely tender and possibly painful when touched (signs of inflammation of a vein due to a blood clot, e.g. thrombophlebitis); | | | √ |
| - Difficulty breathing, chest pain, fainting rapid heart rate, bluish skin discoloration (signs of blood clot formation in the lung such as pulmonary embolism); | | | √ |
| - Swelling of arms, hands, feet, ankles or other parts of the body (signs of oedema); | | | √ |
| - Swelling mainly of the face and throat (signs of allergic reaction); | | | √ |
| - Severe fever, chills or mouth ulcers due to infections (signs of low level of white blood cells); | | | √ |
| - Blurred vision (sign of cataract); | | | √ |
| - Yellow skin and eyes, nausea, loss of appetite, dark-coloured urine (signs of hepatitis); | | | √ |
| rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (signs of skin disorder). | | | √ |

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

## HOW TO STORE IT

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 and pets.

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.

### REPORTING SUSPECTED SIDE EFFECTS

**You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:**

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- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  **- Fax toll-free to 1-866-678-6789, or**
  **- Mail to: Canada Vigilance Program**
  **Health Canada**
  **Postal Locator 0701E**
  **Ottawa, Ontario**
  **K1A 0K9**

**Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.**

***NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.***

## MORE INFORMATION

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

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

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