**Sandoz® Letrozole**

(Getrozole)

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

Sandoz Letrozole, for use as adjuvant treatment of postmenopausal women with hormone receptor-positive early breast cancer and as extended adjuvant treatment of hormone receptor-positive early breast cancer in postmenopausal women who have received approximately 5 years of prior standard adjuvant tamoxifen therapy, has been approved with conditions, pending the results of studies to verify its clinical benefit. For more information, patients are advised to contact their health care provider.

**What a Notice of Compliance with Conditions (NOC/c)?**

An NOC/c is a form of market approval granted to a product on the basis of promising evidence of clinical effectiveness following review of the submission by Health Canada. Products approved under Health Canada’s NOC/c policy are intended for the treatment, prevention or diagnosis of a serious, life-threatening or severely debilitating illness. They have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment. In addition, they either respond to a serious unmet medical need in Canada or have demonstrated a significant improvement in the benefit/risk profile over existing therapies. Health Canada has provided access to this product on the condition that sponsors carry out additional clinical trials to verify the anticipated benefit within an agreed upon time frame.

**ABOUT THIS MEDICATION**

**What Sandoz Letrozole is used for:**

- The adjuvant treatment of postmenopausal women with hormone receptor-positive early breast cancer.
- The extended adjuvant treatment of hormone receptor-positive 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.
- The hormonal treatment of advanced metastatic breast cancer in women with natural or artificially-induced postmenopausal status, who have disease progression following antiestrogen therapy.

**What does Sandoz Letrozole do:**

Estrogen is a normally occurring female sex hormone that stimulates normal breast tissue and the growth of some types of breast cancer. Sandoz Letrozole 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 Sandoz Letrozole 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 Sandoz Letrozole 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 Sandoz Letrozole beyond the standard 5 years of hormone therapy is called “extended adjuvant therapy”.

**When it should not be used:**

Sandoz Letrozole should not be used in children and adolescents under 18 years of age. Do not take Sandoz Letrozole if you:

- have ever had an unusual or allergic reaction to letrozole or any other ingredient in Sandoz Letrozole;
- still have menstrual periods;
- are pregnant or breast-feeding, as Sandoz Letrozole may harm your baby.

**What the medicinal ingredient is:**

Letrozole

**What the nonmedicinal ingredients are:**

Sandoz Letrozole also contains the following non-medical 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:**

Sandoz Letrozole (letrozole) 2.5 mg tablets

Sandoz Letrozole 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.

Sandoz Letrozole is supplied in blister packs containing 30 tablets.

**WARNINGS AND PRECAUTIONS**

**Serious Warnings and Precautions**

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

Sandoz Letrozole 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 Sandoz Letrozole, 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 Sandoz Letrozole if you may become pregnant, are pregnant and/or breast-feeding. 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 postmenopausal), you should discuss with your doctor about the need for effective contraception.

If there is exposure to Sandoz Letrozole 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.

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

**Before you take Sandoz Letrozole:**

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. Sandoz Letrozole may increase lipid levels;
- have or have had cardiovascular or heart disease including any of the following: heart attack, stroke or uncontrolled blood pressure. Sandoz Letrozole may increase the risk of cardiovascular or heart diseases;
- have an intolerance to milk sugar (lactose).

**Driving a vehicle or using machinery:**

Sandoz Letrozole 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 Sandoz Letrozole.

**PROPER USE OF THIS MEDICATION**

**Usual Dose:**

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

**Overdose:**

If overdose 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 Sandoz Letrozole, 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 dose to make up for the one that you missed.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like all medicines, Sandoz Letrozole can have some side effects. 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 the lack of estrogen in your body.

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

- hot flushes
- night sweat
- pain in bones and joints
Common side effects (they affect between 1 to 10 in every 100 patients)
- headache
- rash
- dizziness
- generally feeling unwell
- 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
- bone fractures
- depression
- weight increase
- memory problems
- anxiety
- insomnia
- hair loss
- fatigue
- increased sweating
- high level of cholesterol (hypercholesterolemia)

Uncommon side effects (they affect between 1 to 10 in every 1000 patients)
- nervous disorders (such as nervousness, irritability, drowsiness)
- reduced sense of touch (dysesthesia)
- eye irritation
- palpitations, rapid heart rate
- raised blood pressure (hypertension)
- dry skin, itchy rash (urticaria), rapid swelling of face, lips, tongue, throat (angioedema)
- severe allergic reaction (anaphylactic reaction)
- vaginal disorders (such as bleeding, discharge or dryness)
- abdominal pain
- joint stiffness (arthritis)
- 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)

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

<table>
<thead>
<tr>
<th>Symptom/effect</th>
<th>Talk with your doctor or pharmacist</th>
<th>Stop taking drug and call your doctor or pharmacist</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Common</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain in the muscles, bones and joints</td>
<td>✔</td>
<td></td>
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<tr>
<td>Joint stiffness</td>
<td>✗</td>
<td></td>
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<tr>
<td>Persistent sad mood (i.e. depression)</td>
<td>✗</td>
<td>✔</td>
</tr>
<tr>
<td><strong>Uncommon</strong></td>
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<tr>
<td>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)</td>
<td>✗</td>
<td>✔</td>
</tr>
<tr>
<td>Numbness 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)</td>
<td>✗</td>
<td>✔</td>
</tr>
<tr>
<td>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)</td>
<td>✗</td>
<td>✔</td>
</tr>
<tr>
<td>Difficulty breathing, chest pain, fainting, rapid heart rate, blush skin discolouration (signs of blood clot formation in the lung such as pulmonary embolism)</td>
<td>✗</td>
<td>✔</td>
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<tr>
<td>Swelling of arms, hands, feet, ankles or other parts of the body (signs of oedema)</td>
<td>✗</td>
<td>✔</td>
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<tr>
<td>Severe fever, chills or mouth ulcers due to infections (signs of low level of white blood cells)</td>
<td>✗</td>
<td>✔</td>
</tr>
<tr>
<td>Blurred vision (sign of cataract)</td>
<td>✗</td>
<td>✔</td>
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</table>

This is not a complete list of side effects. For any unexpected effects while taking Sandoz Letrozole, 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 Sandoz Letrozole 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:
- 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 0701C
    Ottawa ON 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.sandoz.ca](http://www.sandoz.ca)
or by contacting the sponsor, Sandoz Canada Inc., at: 1-800-361-3062 or by written request at: 145, Jules-Léger, Boucherville (QC) Canada J4B 7K8 or by e-mail at: medinfo@sandoz.com
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