

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **AROMASIN**<sup>®</sup>

#### Exemestane Tablets

Read this carefully before you start taking **AROMASIN** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **AROMASIN**.

#### Serious Warnings and Precautions

AROMASIN should be taken under the supervision of a qualified doctor experienced in the use of anti-cancer agents.

- AROMASIN is NOT recommended for use in pre-menopausal women.
- The use of estrogen lowering agents, including AROMASIN, may cause bone loss. Women with osteoporosis (brittle bones), or at high risk of osteoporosis should be carefully monitored by their doctor. These women may require treatment for osteoporosis or treatment to prevent osteoporosis while receiving AROMASIN.

#### What is AROMASIN used for?

AROMASIN is used for the:

- adjuvant treatment of early breast cancer in postmenopausal women who had been treated previously with tamoxifen for 2 to 3 years.
- treatment of advanced breast cancer in postmenopausal women who had been treated previously with antiestrogens (for example, tamoxifen).

#### How does AROMASIN work?

AROMASIN blocks the activity of an enzyme called aromatase. This enzyme is needed to make the female sex hormone, estrogen, especially in postmenopausal women. As a result, the amount of estrogen in the body is reduced. This is helpful because estrogen may influence the growth of certain types of breast cancer cells.

#### Adjuvant treatment

Adjuvant means “in addition to”. In early breast cancer, this means that additional treatment is required after primary treatment. The reason for this is that after surgery, a small number of cancer cells may remain in the body. These cells can continue to multiply and spread. Adjuvant therapy is given to prevent or delay these cells from multiplying and spreading.

#### What are the ingredients in AROMASIN?

Medicinal ingredients: exemestane.

Non-medicinal ingredients: carnauba wax, cetyl esters wax, crospovidone, hydroxypropyl methylcellulose, iron oxides, magnesium carbonate, magnesium stearate, mannitol, methyl-p-hydroxybenzoate, microcrystalline cellulose, polyethylene glycol 6000, polysorbate 80, polyvinyl

alcohol, shellac, silicon dioxide, simethicone, sodium starch glycolate, sucrose, talc, titanium oxide.

**AROMASIN comes in the following dosage forms**

Tablets: 25 mg

The tablets are round and off-white to slightly gray in color.

**Do not use AROMASIN if:**

- you are allergic to exemestane or any other ingredients in AROMASIN.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take AROMASIN. Talk about any health conditions or problems you may have, including if you:**

- have previously had an allergic reaction to exemestane or any of the other ingredients of AROMASIN (listed above).
- are still having your period. AROMASIN is only for use in women who are past menopause.
- are pregnant or likely to be pregnant. AROMASIN may cause harm to your unborn baby.
- are breast-feeding. It is not known if AROMASIN passes into breast milk.
- have or have had kidney disease.
- have or have had liver disease.
- have or have had cardiovascular or heart disease including any of the following: heart attack, stroke or uncontrolled blood pressure.
- have or have had high cholesterol.
- have been diagnosed with osteoporosis (bone thinning) or have had a bone fracture related to osteoporosis. This is because AROMASIN may cause bone loss.

**Other warnings you should know about:**

- If you are taking AROMASIN and your doctor has prescribed hormone replacement therapy (HRT) or estrogen, you should discuss this with your doctor. AROMASIN should not be taken together with agents that have estrogen. This may affect the effectiveness of AROMASIN.
- Treatment with AROMASIN may increase your risk of certain side effects, such as:
  - **Cardiovascular diseases**, including heart attack, heart failure and high blood pressure (hypertension).
  - **Hypercholesterolemia** (high blood cholesterol levels). Your healthcare professional will monitor your cholesterol levels during treatment with AROMASIN.
  - **Gastric ulcer**. Your doctor may give you another medicine to help treat this side effect.
  - **Serious skin problems**. Tell your healthcare professional right away if you have severe skin reactions while taking AROMASIN. Your doctor may need to stop your treatment with AROMASIN.

### **Driving and using machines**

AROMASIN can make you feel drowsy, dizzy or weak. Before engaging in activities that require special attention, wait until you know how AROMASIN affects you.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

### **The following may interact with AROMASIN:**

#### *Switching from tamoxifen to AROMASIN*

- If you are taking tamoxifen and warfarin and your doctor switches you to AROMASIN, your dose of warfarin may need to be adjusted.

AROMASIN and other medication may affect each other. During treatment, do NOT start taking any new medicine without checking first with your doctor or pharmacist.

### **How to take AROMASIN:**

- Take AROMASIN exactly as your healthcare professional tells you.
- Take by mouth, once a day.
- AROMASIN should be taken with food (after a meal).
- Try to take AROMASIN at the same time each day.
- Your doctor will discuss with you how long you will take AROMASIN.

### **Usual dose:**

The recommended dose is 25 mg (one tablet), once a day.

### **Overdose:**

If you think you, or a person you are caring for, have taken too much AROMASIN, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

### **Missed Dose:**

If you forget to take a dose of AROMASIN, 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 double dose to make up for the dose you missed.

### **What are possible side effects from using AROMASIN?**

These are not all the possible side effects you may have when taking AROMASIN. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Hot flushes
- Nausea
- Fatigue

- Dizziness
- Pain in bones and joints (arthralgia)
- Depression
- Excessive sweating
- Headache
- Abdominal pain
- Sleeplessness
- Skin rash
- Increase of appetite
- Muscle and joint pain
- Constipation
- Weight gain
- Hair loss
- Diarrhea
- Indigestion
- High cholesterol
- Pain or burning sensation in the hands or wrists (carpal tunnel syndrome)
- Hives
- Itchiness
- Infections of the urinary tract
- Abnormal liver function test results (blood test disorders)

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>COMMON</b>			
<b>Hypertension</b> (high blood pressure): shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
and skin, racing pulse or heart palpitations			
<b>Osteoporosis</b> (thin, fragile bones): broken bones, pain, back pain that gets worse when standing or walking		√	
<b>Peripheral edema</b> (swelling of the legs or hands caused by fluid retention): swollen or puffy legs or hands, feeling heavy, achy or stiff		√	
Vaginal Bleeding		√	
<b>UNCOMMON</b>			
Chest Pain in association with shortness of breath and sensation of fullness/ heaviness		√	√
<b>Gastric ulcer:</b> Burning stomach pain, heart burn, nausea or vomiting that could progress to blood in stools, black tarry stools or vomiting of blood		√	√
<b>Hypersensitivity</b> (including anaphylactic reactions)		√	√
<b>Neuropathy</b> (nerve damage): pain, burning, or numbness		√	
<b>Tendon disorders including tendonitis</b> (inflammation of the tendon) <b>and tenosynovitis</b> (inflammation of the tissue surrounding the tendon): pain, swelling and tenderness near a joint		√	
<b>RARE</b>			

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Allergic Reaction:</b> skin rash, swelling, difficulty breathing			√
<b>Hepatitis</b> (inflammation of liver): Yellowing of the skin or eyes, nausea, loss of appetite, dark-coloured urine		√	√
<b>Tendon tears:</b> feel a snap or pop when the tear happens, severe pain, swelling		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

#### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

#### Storage:

- Keep AROMASIN in the original package and store at room temperature (between 15 to 30°C). Avoid places where the temperature may rise above 30°C.
- Before use, check the expiry date printed on the pack. Do not use after this date. Remember to take any unused medication back to your pharmacist.
- Keep out of reach and sight of children.

#### If you want more information about AROMASIN:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website:

(<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website [www.pfizer.ca](http://www.pfizer.ca) or by calling 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC

Last Revised NOV 25, 2022