IMPORTANT: PLEASE READ

PART III:
CONSUMER INFORMATION

Pr ARIMIDEX®
(anastrozole)

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

ABOUT THIS MEDICATION

What ARIMIDEX is used for:
ARIMIDEX is used for the treatment of postmenopausal women with hormone receptor positive breast cancer in the following conditions:

- adjuvant treatment for early breast cancer
- advanced breast cancer

What ARIMIDEX does:
In hormone sensitive breast cancer, estrogens fuel tumour growth. Following menopause, estrogens are still produced in small amounts in other tissues of the body such as the breasts, muscle and fat. These estrogens are produced when androgens (hormones produced by the adrenal glands) interact with aromatase, a naturally occurring enzyme in the body.

ARIMIDEX belongs to a group of medicines called aromatase inhibitors and works by inhibiting the aromatase enzyme, thereby, suppressing the production of estrogens that can stimulate tumour growth. Suppressing the production of estrogens may help reduce the growth of breast cancer and delay the breast cancer from recurring.

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. The purpose of adjuvant therapy with ARIMIDEX is to help to delay the breast cancer from recurring. Cytotoxic chemotherapy, radiation, and hormonal treatment are three common forms of adjuvant treatment.

When ARIMIDEX should not be used:

- If you are allergic to the active ingredient anastrozole or any nonmedicinal ingredients of ARIMIDEX. If you think you may be allergic, ask your doctor for advice.
- If you are pregnant or breast-feeding.

What the medicinal ingredient is:
anastrozole

What the important nonmedicinal ingredients are:
lactose monohydrate, povidone, sodium starch glycolate, magnesium stearate, hypromellose, macrogol 300 and titanium dioxide.

What dosage forms ARIMIDEX comes in:
Each ARIMIDEX tablet contains 1 milligram of anastrozole.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

ARIMIDEX should not be given to premenopausal women.

ARIMIDEX should not be given to children.

Patients with liver and/or kidney problems, and patients with osteoporosis or at risk for osteoporosis should be carefully monitored by the doctor.

ARIMIDEX should be prescribed by a doctor experienced in the use of anti-cancer drugs.

BEFORE you use ARIMIDEX talk to your doctor or pharmacist:

- If you have any disorder or disease which affects your heart, liver or kidneys.
- ARIMIDEX lowers the level of female hormones and this may lead to a loss of mineral content of bones, which might decrease their strength and lead to a broken bone. You should talk to your doctor about your osteoporosis risk before using ARIMIDEX.

ARIMIDEX tablets are unlikely to affect your ability to drive a car or to operate machinery. However, some patients may occasionally feel weak or sleepy. If this happens, you should not drive or operate machinery.

INTERACTIONS WITH ARIMIDEX

BEFORE you use ARIMIDEX talk to your doctor or pharmacist:

- If you take medicine containing estrogen (a female sex hormone). It may oppose the effect of ARIMIDEX. Some herbal products contain estrogen.
- If you are currently taking tamoxifen.
- If you are taking or have recently taken other medicines, even those not prescribed by a doctor.

Please note that these statements may also apply to medicine used some time ago.

PROPER USE OF ARIMIDEX

Usual dose:
Follow your doctor's instructions about when and how to take your ARIMIDEX tablets. The usual dose is one tablet once a day. Swallow the tablet with fluids. Try to take your tablet at the same time each day.

For adjuvant treatment of early breast cancer, currently it is recommended that ARIMIDEX be taken for 5 years.

Overdose:
If you take more than your normal dose of ARIMIDEX, contact your doctor, pharmacist, regional poison control centre or nearest hospital.

Missed Dose:
Take the last missed dose as soon as you remember, as long as it is at least 12 hours before the next dose is due.
If it is less than 12 hours to the next dose, do not take the dose you have missed.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, ARIMIDEX can have side effects.

Contact your doctor immediately if any of the following happens to you. You may need further examinations or treatment:

- Severe skin reactions (Stevens-Johnson syndrome) with lesions, ulcers or blisters. This type of skin reaction is very rare.
- Allergic reaction with swelling of the face, lips, tongue and/or throat which may cause difficulty in swallowing and/or breathing.
- Chest pain or angina, as a result of ischemic heart disease (reduced blood flow in the vessels of the heart).
- Inflammation of the liver (hepatitis). Symptoms may include a general feeling of being unwell, with or without jaundice (yellowing of the skin and eyes) and pain in the upper abdomen on the right side.
- If you experience nausea, vomiting and thirst, you should tell your doctor. These symptoms may indicate possible increased blood calcium levels.

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

Symptom / effect	Talk with your doctor or pharmacist in all cases	Stop taking drug and call your doctor or pharmacist
Very Common (greater than or equal to 10 of every 100 patients are likely to have these events)		
Hot flushes	√	
Joint pain, joint stiffness or broken bones	√	
Common (greater than or equal to 1 of every 100 patients, but less than 10 of every 100 patients, are likely to have these events)		
Weakness	√	
Carpal tunnel syndrome (tingling, pain, coldness, weakness in parts of the hand)	√	
Tickling, tingling or numbness of skin, loss/ lack of taste	√	
Vaginal dryness	√	
Hair thinning (alopecia)	√	
Rash	√	
Nausea	√	
Diarrhea	√	
Headache	√	
Changes in blood tests of liver function	√	
Bone pain	√	
Muscle pain	√	
Uncommon (greater than or equal to 1 of every 1000 patients, but less than 10 of every 1000 patients, are likely to have these events)		
Vaginal bleeding	√	
Loss of appetite	√	
High blood cholesterol	√	
Vomiting	√	
Sleepiness/tiredness	√	
Trigger finger	√	
Hepatitis	√	√

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

Symptom / effect	Talk with your doctor or pharmacist in all cases	Stop taking drug and call your doctor or pharmacist
Very Rare (less than 1 of every 10 000 patients are likely to have these events)		
Severe skin reactions	√	√
Allergic reactions	√	√

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

HOW TO STORE IT

- Keep out of reach and sight of children.
- Store at room temperature, 15 to 30°C.
- Keep your ARIMIDEX tablets in the original container.
- Do not use ARIMIDEX after the expiry date on the blister package.

REPORTING SUSPECTED SIDE EFFECTS

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:

- 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, 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

NOTE: This INFORMATION FOR THE CONSUMER leaflet provides you with the most current information at the time of printing.

For the most current information, the Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be found at: www.astrazeneca.ca,
or by contacting the sponsor, AstraZeneca Canada Inc. at:
Customer Inquiries – 1 (800) 668-6000,
Renseignements – 1 (800) 461-3787.

This leaflet was prepared by:
AstraZeneca Canada Inc. Mississauga, Ontario L4Y 1M4

Last revised: January 19, 2018