

FDA-Approved Patient Labeling
PATIENT INFORMATION

ARIMIDEX[®]
(*anastrozole*) (an as' troe zole)
Tablets

Read the information that comes with ARIMIDEX before you start taking it and each time you get a refill. The information may have changed. This leaflet does not take the place of talking with your doctor about your medical condition or treatment. Talk with your doctor about ARIMIDEX when you start taking it and at regular checkups.

What is ARIMIDEX?

ARIMIDEX is a prescription medicine used in women who have finished menopause (“the change of life”) for:

- treatment of early breast cancer
 - after surgery, with or without radiation
 - in women whose breast cancer is hormone receptor-positive
- first treatment of locally advanced or metastatic breast cancer, in women whose breast cancer is hormone receptor-positive or the hormone receptors are not known.
- treatment of advanced breast cancer, if the cancer has grown, or the disease has spread after tamoxifen therapy.

ARIMIDEX does not work in women with breast cancer who have not finished menopause (premenopausal women).

Who should not take ARIMIDEX?

Do not take ARIMIDEX if you:

- are pregnant, think you may be pregnant, or plan to get pregnant. ARIMIDEX may harm your unborn child. If you become pregnant while taking ARIMIDEX, tell your doctor right away.
- have not finished menopause (are premenopausal).
- are allergic to any of the ingredients in ARIMIDEX. See the end of this leaflet for a list of the ingredients in ARIMIDEX.
- are a man or child.

What is the most important information I should know about ARIMIDEX?

ARIMIDEX may cause serious side effects including:

- **Heart disease.** Women with early breast cancer, who have a history of blockages in heart arteries (ischemic heart disease) and who take ARIMIDEX may have a slight increase in this type of heart disease compared to similar patients who take tamoxifen.

- Stop taking ARIMIDEX and call your doctor right away if you have chest pain or shortness of breath. These can be symptoms of heart disease.
- **Osteoporosis (bone softening and weakening).** ARIMIDEX lowers estrogen in your body, which may cause your bones to become softer and weaker. This can increase your chance of fractures, specifically of the spine, hip and wrist. Your doctor may order a test for you called a bone mineral density study before you start taking ARIMIDEX and during treatment with ARIMIDEX as needed.

What should I tell my doctor before taking ARIMIDEX?

ARIMIDEX may not be right for you. Before taking ARIMIDEX, tell your doctor about all your medical conditions, including if you:

- have not finished menopause. Talk to your doctor if you are not sure. See “Who should not take ARIMIDEX?”
- have had a previous heart problem
- have a condition called osteoporosis
- have high cholesterol
- are pregnant, planning to become pregnant, or breast feeding. See “Who should not take ARIMIDEX?”
- are nursing a baby. It is not known if ARIMIDEX passes into breast milk. You and your doctor should decide if you will take ARIMIDEX or breast feed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your doctor if you take:

- **Tamoxifen.** You should not take **ARIMIDEX** with tamoxifen. Taking tamoxifen with ARIMIDEX may lower the amount of ARIMIDEX in your blood and may cause ARIMIDEX not to work as well.
- **Medicines containing estrogen.** ARIMIDEX may not work if taken with one of these medicines:
 - hormone replacement therapy
 - birth control pills
 - estrogen creams
 - vaginal rings
 - vaginal suppositories

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist each time you get a new medicine.

How should I take ARIMIDEX?

- Take ARIMIDEX exactly as prescribed by your doctor. Keep taking ARIMIDEX for as long as your doctor prescribes it for you.
- Take one ARIMIDEX tablet each day.
- ARIMIDEX can be taken with or without food.
- If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose. Take your next regularly scheduled dose. Do not take two doses at the same time.
- If you have taken more ARIMIDEX than your doctor has prescribed, contact your doctor right away. Do not take any additional ARIMIDEX until instructed to do so by your doctor.

Talk with your doctor about any health changes you have while taking ARIMIDEX.

What are possible side effects of ARIMIDEX?

ARIMIDEX can cause serious side effects including:

- See **“What is the most important information I should know about ARIMIDEX?”**
- **increased blood cholesterol (fat in the blood).** Your doctor may check your cholesterol while you take ARIMIDEX therapy.
- **skin reactions.** Stop taking ARIMIDEX and call your doctor right away if you get any skin lesions, ulcers, or blisters.
- **severe allergic reactions.** Get medical help right away if you have:
 - swelling of the face, lips, tongue, or throat.
 - trouble swallowing
 - trouble breathing
- **liver problems.** ARIMIDEX can cause inflammation of the liver and changes in blood tests of the liver function. Your doctor may monitor you for this. Stop taking ARIMIDEX and call your doctor right away if you have any of these signs or symptoms of a liver problem:
 - a general feeling of not being well
 - yellowing of the skin or whites of the eyes
 - pain on the right side of your abdomen

Common side effects in women taking ARIMIDEX include:

- hot flashes
- weakness
- joint pain
- carpal tunnel syndrome (tingling, pain, coldness, weakness in parts of the hand)
- pain
- sore throat
- mood changes
- high blood pressure
- depression
- nausea and vomiting
- thinning of the hair (hair loss)
- rash
- back pain

- sleep problems
- bone pain
- headache
- swelling
- increased cough
- shortness of breath
- lymphedema (build up of lymph fluid in the tissues of your affected arm)
- trigger finger (a condition in which one of your fingers or your thumb catches in a bent position)

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

HOW SHOULD I STORE ARIMIDEX?

- Store ARIMIDEX at 68°F to 77°F (20°C to 25°C).
- Keep ARIMIDEX and all medicines out of the reach of children.

General information about ARIMIDEX.

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not take ARIMIDEX for a condition for which it was not prescribed. Do not give ARIMIDEX to other people, even if they have the same symptoms you have. It may harm them.

This patient information leaflet summarizes the most important information about ARIMIDEX. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about ARIMIDEX that is written for health professionals. For more information call 1-866-992-9276 or go to www.ARIMIDEX.com.

What are the ingredients in ARIMIDEX?

Active ingredient: anastrozole

Inactive ingredients: lactose, magnesium stearate, hydroxypropylmethylcellulose, polyethylene glycol, povidone, sodium starch glycolate, and titanium dioxide.

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