



1.5 Product Information

1.5.3 Patient information leaflet

(For All Products not subject to Medical Prescription)

ANATERO (Anastrozole Tablets 1 mg)

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If you get any side effects, talk to your doctor or pharmacist.

In this leaflet:

1. What Anastrozole is and what it is used for
2. What you need to know before you take Anastrozole
3. How to take Anastrozole
4. Possible side effects
5. How to store Anastrozole
6. Contents of the pack and other information

1. WHAT AN ANASTROZOLE TABLETS 1 MG IS AND WHAT IT IS USED FOR

ANATERO is a prescription medicine used in women after menopause (“the change of life”) for:

Treatment of early breast cancer

- after surgery
- in women whose breast cancer is hormone receptor-positive

The first treatment of breast cancer that has spread to nearby tissue or lymph nodes (locally advanced) or has spread to other parts of the body (metastatic), 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

ANATERO does not work in women with breast cancer who have not gone through menopause (premenopausal women).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ANASTROZOLE TABLETS 1 MG

Do not take Anastrozole:

- Are pregnant or able to become pregnant. ANATERO may harm your unborn baby. If you become pregnant while taking ANATERO, tell your doctor right away.
- have not gone through menopause (are premenopausal)
- Have had a severe allergic reaction to Anastrozole or any of the ingredients in ANATERO. See the end of this leaflet for a complete list of ingredients in ANATERO. Symptoms of a severe allergic reaction to ANATERO include: swelling of the face, lips, tongue, or throat, trouble breathing or swallowing, hives and itching.

Warnings and precautions

Talk to your doctor or pharmacist before taking Anastrozole:

- have not gone through menopause. Talk to your doctor if you are not sure.
- have or had a heart problem
- have been told you have bone thinning or weakness (osteoporosis)
- have high cholesterol
- have any other medical conditions
- are pregnant or plan to become pregnant. ANATERO may harm your unborn baby. See “Who should not take ANATERO?”
- are breastfeeding or plan to breastfeed. It is not known if ANATERO passes into breast milk. You and your doctor should decide if you will take ANATERO or breastfeed. You should not do both.

Other medicines and Anastrozole

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

- **Tamoxifen.** You should not take **ANATERO** if you take tamoxifen. Taking ANATERO with tamoxifen may lower the amount of ANATERO in your blood and may cause ANATERO not to work as well.



- Medicines that contain estrogen.

ANATERO may not work if taken with any 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 to show your doctor and pharmacist when you get a new medicine.

3. HOW TO TAKE ANASTROZOLE TABLETS 1 MG

- Take ANATERO exactly as your doctor tells you to take it.
- Continue taking ANATERO until your doctor tells you to stop.
- ANATERO 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 take too much ANATERO, call your doctor or go to the nearest hospital emergency room right away.

4. POSSIBLE SIDE EFFECTS

ANATERO may cause serious side effects including:

- See “What is the most important information I should know about ANATERO?”
- Bone thinning or weakness (osteoporosis). ANATERO lowers estrogen in your body, which may cause your bones to become thinner and weaker. This may increase your risk of fractures, especially of your spine, hip and wrist. Your doctor may order a bone mineral density test before you start and during treatment with ANATERO to check you for bone changes.
- Increased blood cholesterol (fat in the blood). Your doctor may do blood tests to check your cholesterol while you are taking ANATERO.
- Skin reactions. Stop taking ANATERO 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 get:

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- swelling of your face, lips, tongue, or throat
- trouble swallowing or breathing
- Liver problems. ANATERO can cause inflammation of your liver and changes in liver function blood tests. Your doctor may check you for this.
- Stop taking ANATERO 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 your skin or whites of your eyes
 - Pain on the right side of your stomach-area (abdomen)

Common side effects in women taking ANATERO include:

- hot flashes
- weakness
- joint aches
- joint pain, stiffness or swelling (arthritis)
- pain
- sore throat
- high blood pressure
- depression
- nausea and vomiting
- rash
- back pain
- sleep problems
- bone pain
- headache
- swelling of your legs, ankles, or feet
- increased cough
- shortness of breath
- buildup of lymph fluid in the tissues of your affected arm (lymphedema)

Tell your doctor if you have any side effect that bothers you or that does not go away.



These are not all the possible side effects of ANATERO. For more information, ask your doctor or pharmacist.

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

5. HOW TO STORE ANASTROZOLE TABLETS 1 MG

Store below 30°C and protect from moisture.

Keep ANATERO and all medicines out of the reach of children.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Anastrozole tablets 1mg contains

The active substance is Anastrozole. Each film coated tablet contains 1 mg of Anastrozole USP.

The other ingredients are lactose monohydrate, Povidone, sodium starch glycolate, Isopropyl alcohol, Magnesium Stearate and Opadry white Y-1-7000.

What Anastrozole tablets 1mg looks like and contents of the pack

White colored, round shaped, biconvex film coated tablets, debossed with '1' on one side and 'H' on the other side.

Anastrozole tablets 1mg are available in:

Container pack: 30's HDPE Container and 3x 10's Blister pack (Alu-PVC)

Marketing Authorization Holder and Manufacturer

Marketing Authorisation Holder:

Name: Hetero Labs Limited

Business Address : 7-2-A2, Hetero Corporate,
Industrial Estates,
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Manufacturer:

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