

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **ANASTROZOLE**

Anastrozole Tablets

Read this carefully before you start taking **ANASTROZOLE** 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 **ANASTROZOLE**.

Serious Warnings and Precautions

- ANASTROZOLE should not be taken by premenopausal women.
- You will be carefully monitored by a healthcare professional while taking ANASTROZOLE if you have:
 - Liver and/or kidney problems;
 - Osteoporosis (bone thinning) or risk factors for osteoporosis.

What is ANASTROZOLE used for?

ANASTROZOLE 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.

How does ANASTROZOLE work?

In hormone sensitive breast cancer, estrogens stimulate tumour growth. Following menopause, estrogens continue to be produced in small amounts in other body tissues such as the breasts, muscle and fat.

ANASTROZOLE belongs to a group of medicines called aromatase inhibitors. It blocks the action of aromatase, an enzyme needed in the production of estrogens. This may help reduce the growth of breast cancer and delay the breast cancer from recurring.

Adjuvant therapy: 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.

Adjuvant therapy is given to prevent or delay these cells from multiplying and spreading. The purpose of adjuvant therapy with ANASTROZOLE is to help to delay the breast cancer from recurring.

What are the ingredients in ANASTROZOLE?

Medicinal ingredients: anastrozole

Non-medicinal ingredients: cellulose microcrystalline, hydroxypropylcellulose, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, macrogol 4000, sodium starch glycolate, silica colloidal anhydrous and titanium dioxide.

ANASTROZOLE comes in the following dosage forms:

Tablets: 1 mg

Do not use ANASTROZOLE if:

- You are allergic to anastrozole or any other ingredients of ANASTROZOLE. If you think you may be allergic, ask your healthcare professional for advice.
- You are pregnant or breast-feeding.

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

- Have any disorder or disease which affects your heart, liver or kidneys.
- Have a disorder or a disease which affects bone density. ANASTROZOLE lowers the level of female hormones which may cause a loss of mineral content of bones. This might make the bones weaker and lead to a broken bone. You should talk to your healthcare professional about your osteoporosis risk before using ANASTROZOLE.

Other warnings you should know about:

Muscle and bone problems: ANASTROZOLE may cause joint stiffness, arthritis or muscle pain.

Driving and using machines: ANASTROZOLE is unlikely to affect your ability to drive a car or use machines. However, some patients may feel weak or sleepy. If this happens, avoid driving or using machinery.

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 ANASTROZOLE:

- Medicine containing estrogen (a female sex hormone). It may oppose the effect of ANASTROZOLE. Some herbal products contain estrogen.
- Tamoxifen, used to treat patients with early-stage, locally advanced or metastatic breast cancer.

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

How to take ANASTROZOLE:

- Take ANASTROZOLE exactly as your healthcare professional has told you.
- Swallow the tablet with fluids.
- Try to take your tablet at the same time each day.

To help you keep track of your doses, ANASTROZOLE comes in a blister pack with days of the week printed on the back of the blister. To start, take the tablet that matches the day of the week and continue taking them in order until they are all finished.

There are 14 days of labeled tablets in each blister, with one extra to make 15. All 15 tablets, including the one labeled "Take this tablet last", are exactly the same. Once you have finished the 14 labeled tablets, take the one marked "Take this tablet last" before starting your next blister pack.

Usual dose:

The usual dose is 1 mg (one tablet) once a day.

Take ANASTROZOLE for as long as your healthcare professional tells you to.

Overdose:

If you think you, or a person you are caring for, have taken too much ANASTROZOLE, 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 ANASTROZOLE, and your next dose is in:

- Less than 12 hours, skip the dose you have missed.
- 12 hours or more, take the last missed dose as soon as you remember.

What are possible side effects from using ANASTROZOLE?

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

- Hot flushes
- Joint pain, joint stiffness or broken bones
- 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 liver function (shown in blood tests)
- Bone pain
- Muscle pain
- Loss of appetite
- Vomiting
- Sleepiness/tiredness
- Trigger finger
- High blood cholesterol (shown in blood tests)

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	
VERY COMMON			
Depression: feeling sad, sleeping a lot more or a lot less than usual, changes in weight, withdrawal from social situations, family gatherings and activities with friends, reduced sex drive, and thoughts of death or suicide.		✓	
Osteoporosis (bone loss, thin and fragile bones): broken bones, pain, back pain that is worse with standing or walking.		✓	
COMMON			
Ischemic heart disease (reduced blood flow in the vessels of the heart): chest pain.		✓	✓
UNCOMMON			
Hepatitis (Inflammation of the liver): general feeling of being unwell, with or without yellowing of the skin and eyes, and pain in the upper abdomen on the right side.		✓	✓
Tendon disorders including tendonitis (inflammation of the		✓	

tendon) and tenosynovitis (inflammation of the tissue around the tendon): pain, swelling and tenderness near a joint.			
Vaginal bleeding (usually in the first weeks of treatment).	✓		
RARE			
Tendon tears: feel a snap or pop when the tear happens, severe pain, swelling.		✓	
VERY RARE			
Stevens-Johnson syndrome (Severe skin reactions): lesions, ulcers, blisters.		✓	✓
Allergic reactions: swelling of the face, lips, tongue and/or throat, with or without difficulty in swallowing and/or breathing.		✓	✓

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/adverse-reaction-reporting.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:

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

If you want more information about ANASTROZOLE:

- 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.sivem.ca or by calling 1 855-788-3153.

This leaflet was prepared by Sivem Pharmaceuticals ULC

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