

Consumer Medicine Information

ANASTROZOLE

Anastrozole USP Tablets

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Anastrozole Sandoz.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you taking Anastrozole Sandoz against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.
You may want to read it again.

WHAT ANASTROZOLE IS USED FOR

The name of your medicine is Anastrozole Sandoz. It contains the active ingredient anastrozole. Anastrozole Sandoz is used to treat breast cancer in women who are postmenopausal (i.e. women who no longer have their menstrual periods).

Ask your doctor if you have any questions about why Anastrozole Sandoz was prescribed for you. Your doctor may have prescribed Anastrozole Sandoz for another reason.

How Anastrozole Sandoz Works

Anastrozole Sandoz belongs to a group of medicines called nonsteroidal aromatase inhibitors. Anastrozole Sandoz is a nonsteroidal aromatase inhibitor, which reduces the amount of oestrogen (female sex hormone) made by the body in

postmenopausal women. In some types of breast cancer, oestrogen can help the cancer cells grow. By blocking oestrogen,

Anastrozole Sandoz may slow or stop the growth of cancer. Anastrozole Sandoz should only be taken by postmenopausal women.

Anastrozole Sandoz is not recommended for use in men, children or women who are not postmenopausal. There is no evidence that Anastrozole is addictive.

BEFORE YOU TAKE ANASTROZOLE

When you must not take it

Do not take Anastrozole Sandoz if:

- * you are allergic to the active ingredient or any of the inactive

ingredients mentioned at the end of this leaflet under Product Description

- * you have an allergy to other antioestrogen medicines
- * it is past its expiry date or the packaging appears to have been tampered with
- * you are pregnant or breastfeeding
- * you are still having menstrual periods (i.e. you have not yet reached menopause)
- * you are a man.

Anastrozole is not recommended for use in children or in premenopausal women as safety and efficacy have not been established in these groups of patients.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to:

- * any other medicines, especially if they are in the same drug class as anastrozole
- * any other substances, including foods, preservatives or dyes.

Tell your doctor if you plan on becoming pregnant or will be breast feeding while you are using Anastrozole Sandoz.

Tell your doctor if you have or have had any medical conditions, especially the following medical conditions:

- * liver problems
- * kidney problems
- * osteoporosis, a family history of osteoporosis or risk factors for developing osteoporosis (such as smoking, a diet low in calcium, poor mobility, a slight build or treatment with steroid medicines).

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

In particular, tell your doctor if you take any of the following:

- * tamoxifen or any medicine that contains oestrogen (e.g. medicines used in Hormone Replacement Therapy - HRT). These medicines may reduce the effect of Anastrozole Sandoz.
- * medicines from a class called Luteinising Hormone Releasing Hormone (LHRH) agonists, such as goserelin or leuprorelin.

These medicines may be affected by Anastrozole Sandoz, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

HOW TO TAKE ANASTROZOLE

How much to take

The usual dose is one tablet every day.

When to take it

Take Anastrozole Sandoz at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it. Swallow Anastrozole Sandoz tablets whole, with a glass of water. It does not matter if you take Anastrozole Sandoz before, with or after food.

How long to take it

Continue taking Anastrozole Sandoz for as long as your doctor or pharmacist tells you.

Anastrozole Sandoz helps to control your condition, but does not cure it. Therefore you must take Anastrozole Sandoz every day. Do not stop taking it unless your doctor tells you to - even if you feel better.

If you forget to take your Dose

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist. If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much

Immediately telephone your doctor, or the Poisons Information Centre or go to Accident and Emergency at your nearest hospital, if you think you or anyone else has taken too much Anastrozole Sandoz. Do this even if there are no signs of discomfort or poisoning.

WHILE YOU ARE TAKING ANASTROZOLE

Things you must do

Always follow your doctor's instructions carefully.

- * Tell your doctor if you become pregnant while taking Anastrozole Sandoz.
- * Be sure to keep all your appointments with your doctor so your progress can be checked.
- * Tell any other doctors, dentists and pharmacists who are treating you that you are taking Anastrozole Sandoz.
- * If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Anastrozole Sandoz.
- * If you go into hospital, please let the medical staff know that you are taking Anastrozole Sandoz.

Things you must not do

- * Do not stop taking Anastrozole Sandoz without your doctor's permission.

- * Do not use Anastrozole Sandoz to treat any other complaint unless your doctor says so.
- * Do not give this medication to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

Be careful driving or operating machinery until you know how Anastrozole Sandoz affects you.

This medicine may occasionally cause some people to feel weak or sleepy.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Anastrozole Sandoz.

This medicine helps most postmenopausal women with breast cancer, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of

the time they are not. Side effects may happen at the start of treatment or they may happen after you have been taking your medicine for some time. You may need medical attention if you get some of the side effects.

If you get any side effects do not stop taking this medicine without first talking to your doctor or pharmacist.

Do not be alarmed by the following lists of side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- * hot flushes
- * lack of energy
- * joint pain or stiffness
- * vaginal dryness
- * thinning of hair
- * mild skin rash
- * feeling sick (nausea)

- * diarrhea
- * headache

These are the more common side effects of the medicine. Mostly, these are mild to moderate in nature.

Uncommon side effects can include vaginal bleeding, loss of appetite, vomiting, feeling sleepy and an increase in cholesterol levels or changes in blood tests of liver function. These side effects are generally mild to moderate and often resolve themselves over time.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- * sudden signs of allergy such as shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other parts of the body; rash, itching or hives on the skin
- * extremely severe skin reactions (Stevens-Johnson syndrome) with lesions, ulcers or blisters.

- * liver pain or swelling and/or a general feeling of unwell with or without jaundice (yellowing of the skin and eyes).

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

AFTER USING ANASTROZOLE

Storage

Keep Anastrozole Sandoz in the original packaging until you need to take it.

Store below 30°C. Keep out of the reach of children.

Disposal

Return any unused or out of date medicine to your pharmacist.

PRODUCT DESCRIPTION

What Anastrozole Sandoz looks like

Anastrozole Sandoz 1mg: white, round, biconvex film coated tablet without breaking notch and embossment 'A1' on one side.

Available in blisters of 30 tablets.

Ingredients

Active Ingredient

Each Anastrozole Sandoz 1mg tablet contains 1mg anastrozole

Inactive Ingredients

Each Anastrozole Sandoz 1mg tablet also contains: lactose, cellulose - microcrystalline, sodium starch glycollate type A, magnesium stearate, silica - colloidal anhydrous, hydroxypropylcellulose and opadry II white [lactose, hypromellose, titanium dioxide and macrogol 4000].

Marketing authorisation holder

Taj Accura Healthcare Limited; Ireland

Manufacturer

Anastrozole is made in India by: Taj Pharmaceuticals Limited.

Dosage Forms And Strengths

Anastrozole 1mg tablet (blisters)

Date of preparation

This leaflet was prepared in December 2011.