ANASTROZOLE SANDOZ®

Anastrozole Tablets

Consumer Medicine Information

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 SANDOZ IS USED FOR

Anastrozole Sandoz is used to treat breast cancer in women who no longer have their menstrual periods either naturally, due to their age or after surgery, radiotherapy or chemotherapy.

Anastrozole Sandoz is a nonsteroidal aromatase inhibitor, which reduces the amount of oestrogen (female sex hormone) made by the body. 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.

Follow all directions given by your doctor.

They may differ from the information contained in this leaflet.

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.

Anastrozole Sandoz is only available with a doctor's prescription.

Anastrozole Sandoz is not addictive.

BEFORE YOU TAKE ANASTROZOLE SANDOZ

When you must not take it

Do not take Anastrozole Sandoz if you have an allergy to:

- any medicine containing anastrozole
- any of the ingredients listed at the end of this leaflet
- other anti-oestrogen medicines.

Some of the symptoms of an allergic reaction may include:

- · shortness of breath
- · wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you are pregnant or intend to become pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

Your baby can take in Anastrozole Sandoz from breast milk if you are breastfeeding.

Do not take Anastrozole Sandoz if you are still having menstrual periods.

Anastrozole Sandoz should only be taken by women who are no longer having menstrual periods.

Do not take Anastrozole Sandoz if you are a man.

Men are not normally treated with Anastrozole Sandoz.

Do not give Anastrozole Sandoz to a child.

Anastrozole Sandoz is not recommended for use in children.

Do not take Anastrozole Sandoz after the use by (expiry) date printed on the pack. Do not take Anastrozole Sandoz if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal

Do not use it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else.

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 breastfeeding 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).

Aromatase inhibitors may decrease bone mineral density (BMD) in women who have been through menopause, with a possible increased risk of fractures. Your doctor should discuss with you your treatment options for managing this possible increased risk of fractures.

Aromatase inhibitors may cause inflammation in tendons (see Side effects). At any sign of tendon pain or swelling – rest the painful area and contact your doctor.

If you have not told your doctor about any of the above, tell him/her before you start taking Anastrozole Sandoz.

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, a medicine used to treat breast cancer
- any medicine that contains oestrogen such as medicines used in Hormone Replacement Therapy (HRT) or oral contraceptives
- any health food products that contain natural oestrogens used for post-menopausal symptoms.

 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.

Talk to your doctor or pharmacist if you have any concerns or questions about taking Anastrozole Sandoz.

Your doctor or pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

HOW TO TAKE ANASTROZOLE SANDOZ

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Your doctor or pharmacist will tell you how many tablets you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

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

If you miss a dose, take it as soon as you remember, as long as it is 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.

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 (telephone 13 11 26) 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 SANDOZ

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 unless you have discussed it with your doctor.
- Do not take Anastrozole Sandoz to treat any other complaints unless your doctor tells you to.
- Do not give this medication to anyone else, even if they have the same condition as you.

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.

Ask your doctor or pharmacist to answer any questions you may have.

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
- 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 uncommon or rare

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

- · hot flushes
- · feeling weak or a lack of energy
- · feeling sleepy
- joint pain or stiffness
- · vaginal dryness
- · vaginal bleeding
- thinning of hair (hair loss)
- · mild skin rash
- feeling sick (nausea)
- diarrhoea
- headache
- loss of appetite (anorexia)
- vomiting

- carpal tunnel syndrome (tingling, pain, coldness, weakness in parts of hand)
- · pins and needles
- loss of taste or changing taste of food or drink
- · feeling depressed.

Anastrozole Sandoz may be associated with changes in your blood, urine or liver. Your doctor may want to perform tests from time to time to check on your progress and detect any unwanted side effects.

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

Uncommon side effects can include trigger finger which is a condition in which one of your fingers or your thumb catches in a bent position.

Cases of inflammation of a tendon or tendonitis (connective tissues that connect muscles to bones) have been observed during the use of similar class of medicines, which might also occur during treatment with Anastrozole Sandoz

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.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

AFTER USING ANASTROZOLE SANDOZ

Storage

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

Keep it in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom or near a sink.

Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

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

PRODUCT DESCRIPTION

What Anastrozole Sandoz looks like

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

Available in PVC/Al blisters of 30 tablets.

Ingredients

Active Ingredient

Each Anastrozole Sandoz 1 mg tablet contains 1 mg anastrozole.

Inactive Ingredients

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

Supplier

Anastrozole Sandoz is supplied in Australia by:

Sandoz Pty Ltd 100 Pacific Highway North Sydney, NSW 2060 Australia

Tel: 1800 726 369

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Australian Register Number

Anastrozole Sandoz 1 mg tablet: AUST R 142746 (blisters)

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