APPROVED PIL FOR ANASTROZOLE SANDOZ 1 MG

SCHEDULING STATUS S4

ANASTROZOLE SANDOZ 1 mg (film-coated tablet)

Anastrozole

Contains sugar (lactose monohydrate 64,7 mg).

Read all of this leaflet carefully before you start taking ANASTROZOLE SANDOZ 1 mg

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ANASTROZOLE SANDOZ 1 mg has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ANASTROZOLE SANDOZ 1 mg is and what it is used for

ANASTROZOLE SANDOZ 1 mg contains a substance called anastrozole. Anastrozole belongs to a group of medicines called ‘aromatase inhibitors’. Anastrozole works by cutting down the amount of the hormone called oestrogen that your body makes. It does this by blocking a natural substance (an enzyme) in your body called ‘aromatase’.

ANASTROZOLE SANDOZ 1 mg is used to treat breast cancer in women who have gone through menopause.

2. What you need to know before you take ANASTROZOLE SANDOZ 1 mg

Do not take ANASTROZOLE SANDOZ 1 mg:

- if you are hypersensitive (allergic) to ANASTROZOLE SANDOZ 1 mg or any of the other ingredients of ANASTROZOLE SANDOZ 1 mg (listed in section 6).
- if you are pregnant, or may become pregnant.
- if you are breastfeeding a baby.
- if you suffer from severe kidney insufficiency.
- if you have moderate or severe hepatic disease.
- if you still have menstrual periods and have not yet gone through the menopause.

Warnings and precautions

Before taking ANASTROZOLE SANDOZ 1 mg, tell your doctor if you have any other medical conditions or if you take other medications. You may not be able to take ANASTROZOLE SANDOZ 1 mg, or you may require a dosage adjustment or special monitoring during treatment.

Take special care:

- if you are taking a medicine that contains tamoxifen or medicines that contain oestrogen (see the section called ‘Other medicines and ANASTROZOLE SANDOZ 1 mg’).
- if you have ever had a condition that affects the strength of your bones (osteoporosis).
- if you have problems with your liver or kidneys.
- if you have vaginal bleeding that is not stopping.

Children and adolescents

ANASTROZOLE SANDOZ 1 mg should not be given to children and adolescents.

Other medicines and ANASTROZOLE SANDOZ 1 mg

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Do not take ANASTROZOLE SANDOZ 1 mg if you are already taking any of the following medicines:

- Certain medicines used to treat breast cancer (selective oestrogen receptor modulators), e.g., medicines that contain tamoxifen.
- Medicines that contain oestrogen, such as hormone replacement therapy (HRT).

This is because these medicines may stop ANASTROZOLE SANDOZ 1 mg from working properly.

There are no known interactions between ANASTROZOLE SANDOZ 1 mg and other medicines.

ANASTROZOLE SANDOZ 1 mg with food, drink and alcohol

There are no restrictions on food, beverages, or activities while taking ANASTROZOLE SANDOZ 1 mg unless otherwise directed by your doctor.

Pregnancy, breastfeeding and fertility

ANASTROZOLE SANDOZ 1 mg is contraindicated during pregnancy or breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

Physical weakness, lack of energy and drowsiness have been reported, therefore caution should be observed when driving or operating machinery while these symptoms persist.

ANASTROZOLE SANDOZ 1 mg contains lactose

ANASTROZOLE SANDOZ 1 mg contains lactose. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take ANASTROZOLE SANDOZ 1 mg.

ANASTROZOLE SANDOZ 1 mg contains lactose which may have an effect on the glycaemic control of patients with diabetes mellitus.

3. How to take ANASTROZOLE SANDOZ 1 mg

Do not share medicines prescribed for you with any other person.

Always take ANASTROZOLE SANDOZ 1 mg exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is 1 tablet once a day, swallowed with a full glass of water. The tablet can be taken with or without food.

If you have the impression that the effect of ANASTROZOLE SANDOZ 1 mg is too strong or too weak, talk to your doctor or pharmacist.

If you take more ANASTROZOLE SANDOZ 1 mg than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison center.

If you forget to take ANASTROZOLE SANDOZ 1 mg

Take the missed dose as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and take only your next regularly scheduled dose.

Do not take a double dose to make up for forgotten individual doses, unless your doctor advises you to do so.

If you stop taking ANASTROZOLE SANDOZ 1 mg

Do not stop taking your tablets unless your doctor tells you to.

4. Possible side effects

ANASTROZOLE SANDOZ 1 mg can have side effects.

Not all side effects reported for ANASTROZOLE SANDOZ 1 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ANASTROZOLE SANDOZ 1 mg, please consult your health care provider for advice.

If any of the following happens, stop taking ANASTROZOLE SANDOZ 1 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- if you experience an allergic reaction (difficulty breathing; closing of your throat; swelling of your lips, tongue, or face; or hives).
- inflammation of the liver (hepatitis) with nausea, vomiting, loss of appetite, fever, itching, yellowing of the skin and eyes, light coloured bowel motions or dark coloured urine.
- rare inflammation of your skin that may include red patches or blisters, known as erythema multiforme.
- an extremely severe skin reaction with ulcers or blisters on the skin. This is known as 'Stevens-Johnson syndrome'.
- inflammation of the small blood vessels causing red or purple colouring of the skin.
- symptoms of joint, stomach, and kidney pain may occur (known as 'Henoch-Schönlein purpura').

These are all very serious side effects. If you have them, you may have had a serious reaction to ANASTROZOLE SANDOZ 1 mg**.** You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- pain or stiffness in your joints.
- inflammation of the joints (arthritis).
- bone loss (osteoporosis).
- headache.
- depression.
- hot flushes.

- weakness, drowsiness.
- muscle or bone pain.
- vaginal dryness.
- vaginal bleeding.
- hair thinning.
- rash.
- nausea or vomiting.
- diarrhoea.
- loss of appetite.
- raised or high levels of a fatty substance known as cholesterol in your blood. This would be seen in a blood test.
- carpal tunnel syndrome (tingling, pain, coldness, weakness in parts of the hand).
- changes in blood tests that show how well your liver is working.

Less frequent side effects:

- raised or high levels of calcium in your blood (seen in a blood test). If you experience nausea, vomiting and thirst, you should tell your doctor or pharmacist as you may need to have blood tests.
- changes in special blood tests that show how your liver is working (gamma-GT and bilirubin).
- hives.
- trigger finger (a condition in which your finger or thumb catches in a bent position).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ANASTROZOLE SANDOZ 1 mg.

Suspected side effects can also be reported directly to the HCR via Patientsafety.sacg@novartis.com.

5. How to store ANASTROZOLE SANDOZ 1 mg

Store at or below 25 °C.

Do not refrigerate or freeze.

Keep the blisters in the outer carton until required for use.

Do not use after the expiry date stated on the carton.

KEEP OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ANASTROZOLE SANDOZ 1 mg contains

Each ANASTROZOLE SANDOZ 1 mg film-coated tablet contains 1 mg anastrozole.

The other ingredients are cellulose microcrystalline, hydroxypropylcellulose, hydroxypropylmethyl cellulose, lactose monohydrate, macrogol 4000, magnesium stearate, silica colloidal anhydrous, sodium starch glycollate and titanium dioxide.

What ANASTROZOLE SANDOZ 1 mg looks like and contents of the pack

ANASTROZOLE SANDOZ 1 mg is a white, round, biconvex film-coated tablet without breaking notch; embossment “A1” on one side.

Diameter: 5,7 to 6,3 mm.

ANASTROZOLE SANDOZ 1 mg is packed in aluminium foil/PVC, clear and colourless blisters.

One blister contains 10 film-coated tablets. One carton contains three blisters.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

The Novartis Building

Magwa Crescent West

Waterfall City, Jukskei View

Gauteng, 2090

South Africa

This leaflet was last revised in

02 September 2022

Registration number

43/21.12/0073

Access to the corresponding Professional Information

Not applicable.

[1]Company Reg. No.: 1990/001979/07