PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

TEVA ANASTROZOLE 1 mg film-coated tablets

Anastrozole

Contains sugar (lactose monohydrate 87,00 mg/film-coated tablet)

Read all of this leaflet carefully before you start taking TEVA ANASTROZOLE 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.
- TEVA ANASTROZOLE 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 TEVA ANASTROZOLE 1 MG IS AND WHAT IT IS USED FOR:

Anastrozole belongs to a group of medicines called aromatase inhibitors. Anastrozole works by interfering with the action of an enzyme called aromatase, which affects the level of oestrogen in the body.

TEVA ANASTROZOLE 1 mg is used in the treatment of advanced breast cancer in post-menopausal

women.

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

Do not take TEVA ANASTROZOLE 1 mg:

- if you are hypersensitive (allergic) to anastrozole or any of the other ingredients of TEVA ANASTROZOLE 1 mg (listed in **section 6**)
- if you are not yet in menopause
- if you are pregnant or breastfeeding a baby
- if you have severe kidney problems
- if you have a moderate or severe liver disease
- if you are taking medicines that contain oestrogen
- if you are taking tamoxifen.

Warnings and precautions:

Special care should be taken with TEVA ANASTROZOLE 1 mg:

- if you still have menstrual periods and have not yet gone through the menopause
- if you are taking oestrogen-containing therapies (medicines used to treat breast cancer, certain gynaecological problems or infertility)
- if you are taking a medicine that contains tamoxifen
- if you have osteoporosis or any condition that affects the strength of your bones. This medicine can reduce your bone density. You should have your bone density checked before you start taking TEVA ANASTROZOLE 1 mg and at regular intervals during treatment
- if you have problems with your liver or kidneys.

Children and adolescents:

Do not give this medicine to children because it is unlikely to be safe.

Other medicines and TEVA ANASTROZOLE 1 mg:

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

Please consult your doctor, pharmacist or other health care professional for advice if you are using any of the following products:

- medicines that contain oestrogen, such as hormone replacement therapy (HRT)
- certain medicines used to treat breast cancer (selective oestrogen receptor modulators), e.g., medicines that contain tamoxifen, this is because these medicines may stop anastrozole from working properly.

TEVA ANASTROZOLE 1 mg with food and drink:

TEVA ANASTROZOLE 1 mg should be swallowed with water, do not chew or crush the tablets.

Pregnancy and breastfeeding:

TEVA ANASTROZOLE 1 mg should not be taken if you are pregnant or breastfeeding your baby.

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 TEVA ANASTROZOLE 1 mg.

Driving and using machines:

TEVA ANASTROZOLE 1 mg may make you feel tired and sleepy. If you experience these symptoms you should refrain from driving or operating machinery.

It is not always possible to predict to what extent TEVA ANASTROZOLE 1 mg may interfere with the daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which TEVA ANASTROZOLE 1 mg affects you.

TEVA ANASTROZOLE 1 mg contains lactose monohydrate:

TEVA ANASTROZOLE 1 mg contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking TEVA ANASTROZOLE 1 mg.

3. HOW TO TAKE TEVA ANASTROZOLE 1 MG:

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

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

Your doctor will tell you how long your treatment with TEVA ANASTROZOLE 1 mg will last. Do not stop treatment early. If you have the impression that the effect of TEVA ANASTROZOLE 1 mg is too strong or too weak, talk to your doctor or pharmacist.

Adults including the elderly:

Take one tablet daily. Swallow with a glass of water.

Children:

TEVA ANASTROZOLE 1 mg is not recommended for children.

If you take more TEVA ANASTROZOLE 1 mg than you should:

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets contact your doctor or pharmacist immediately. Take this leaflet and any remaining tablets with you, so that the doctor knows what the person has taken.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take TEVA ANASTROZOLE 1 mg:

Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS:

TEVA ANASTROZOLE 1 mg can cause side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- a condition in which there is a deficiency of red cells or of haemoglobin in the blood (anaemia)
- a reduction in the number of white cells in the blood (leukopenia with or without infection)
- obstruction of a blood vessel by a blood clot (thromboembolism)
- inflammation of the wall of a vein with associated thrombosis (thrombophlebitis)
- high calcium levels in the blood (hypercalcaemia, with or without an increase in parathyroid hormone)
- chest pain

- difficult breathing (dyspnoea)
- abnormalities in liver enzyme values, increases in alkaline phosphatase, alanine aminotransferase and aspartate aminotransferase.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor of you notice any of the following:

Frequent side effects:

- loss of appetite (anorexia)
- high cholesterol levels (hypercholesterolaemia)
- depression
- dizziness
- headache
- sleepiness (somnolence)
- pins and needles (paraesthesia)
- taste loss and perversion
- a painful condition of the hand and fingers caused by compression of a major nerve where it passes over the carpal bones through a passage at the front of the wrist (carpal tunnel syndrome)
- swelling of your lower legs or hands (peripheral oedema).
- high blood pressure (hypertension)
- becoming red and hot (flushing)
- hot flushes
- cough
- sore throat (pharyngitis)
- constipation
- dry mouth

- stomach pain
- diarrhoea
- nausea
- vomiting
- skin rash
- sweating
- hair thinning (alopecia)
- allergic reactions including nettle rash
- joint pain or stiffness (arthritis)
- pain in a muscle or group of muscles (myalgia)
- back and bone pain
- bone fractures
- a medical condition in which the bones become brittle and fragile from loss of tissue, typically as a result of hormonal changes, or deficiency of calcium or vitamin D (osteoporosis)
- vaginal dryness
- vaginal bleeding
- weakness or lack of energy (asthenia)
- pain
- pain in the lowest part of your abdomen and pelvis (pelvic pain).

Less frequent side effects:

- increased appetite
- weight gain
- anxiety
- confusion

- sleeplessness (insomnia)
- nervousness
- inflammation of the lining of your bronchial tubes, which carry air to and from your lungs (bronchitis)
- inflammation of a nasal sinus (sinusitis) or inflammation of the mucous membrane of the nose (rhinitis)
- changes in special blood tests that show how your liver is working (elevated gamma-GT and bilirubin)
- inflammation of the liver (hepatitis)
- severe itching of the skin (pruritus)
- pink/red rash that may have a clear centre (Erythema multiforme)
- blistering of the skin, eyes and genitals (Stevens-Johnson syndrome)
- swelling beneath your skin (angioedema)
- hives or nettle rash
- inflammation of the small blood vessels causing red or purple colouring of the skin. Very rarely symptoms of joint, stomach, and kidney pain may occur; this is known as 'Henoch-Schönlein purpura'
- trigger finger (a condition in which your finger or thumb catches in a bent position)
- breast pain
- a group of symptoms that are similar to those caused by the influenza (flu) virus. These include fever, chills, headache, muscle or body aches, cough, sore throat, runny nose, fatigue, nausea, vomiting, and diarrhoea (flu syndrome).

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 TEVA ANASTROZOLE 1 mg.

5. HOW TO STORE TEVA ANASTROZOLE 1 MG:

Store at or below 25 ºC. Do not remove blisters from carton until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use the tablets after the expiry date printed on the label or blister.

Return all unused medicine to your pharmacist.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What TEVA ANASTROZOLE 1 mg contains:

The active substance is anastrozole 1 mg.

The other ingredients are lactose monohydrate, povidone, sodium starch glycolate, magnesium stearate, purified water, Opadry 02G28619 containing hypromellose (E464), macrogol 6000, macrogol 400, and titanium dioxide (E171).

Contains sugar (lactose monohydrate).

What TEVA ANASTROZOLE 1 mg looks like and contents of the pack:

White to off white, film-coated round shaped tablet. One side of the tablet debossed with the number '93'. The other side of the tablet debossed with the number 'A10'.

TEVA ANASTROZOLE 1 mg tablets are packed in transparent PVC/PVdC-aluminium blister packs of

30 tablets. The blister strips together with a package insert are packaged into an outer cardboard carton.

Holder of Certificate of Registration:

Teva Pharmaceuticals (Pty) Ltd

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2090

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