PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

EQUISIN, 25 mg film-coated tablets

Exemestane

Contains sugar (mannitol, 40,40 mg per tablet).

Read all of this leaflet carefully before you start taking EQUISIN tablets.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist nurse or other healthcare provider.
- EQUISIN 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 EQUISIN is and what it is used for

The active ingredient in this tablet, exemestane, belongs to a group of medicines known as aromatase inhibitors. Exemestane lowers oestrogen levels in postmenopausal women by irreversibly inactivating the aromatase enzyme responsible for converting androgens into oestrogens.

The function of EQUISIN is to reduce oestrogen levels in the body, it is used to treat:

- Hormone dependent advanced breast cancer in post
- Menopausal women when a different hormonal medicine treatment has not worked well enough.
- Hormone dependent early breast cancer in postmenopausal women after they have completed at least 2 years of treatment with the medicine tamoxifen.

2. What you need to know before you take EQUISIN

Do not take EQUISIN:

- if you are hypersensitive (allergic) to exemestane or any of the other ingredients of EQUISIN (listed in section 6)
- if you have not already been through 'the menopause', i.e., you are still having your monthly period
- if you are pregnant, likely to be pregnant or breastfeeding.

Warnings and precautions

Take special care with EQUISIN:

- EQUISIN may affect the density and strength of your bones. Tell your doctor if you have a history or are suffering from any condition which affects the strength of your bones, such as osteoporosis. Your doctor may want to measure your bone density before and during treatment with EQUISIN.
- Before prescribing EQUISIN, your doctor may want to take blood samples to make sure you already reached menopause.
- Before taking EQUISIN, tell your doctor if you have kidney or liver problems
- Routine checking of your vitamin D level will also be made before treatment, as your level may be very low in the early stages of breast cancer. You will be given vitamin D supplement if your levels are below normal.

Other medicines and EQUISIN

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines)

The blood levels and efficacy of EQUISIN may be reduced if it is taken together with certain medicines. Tell your doctor if you are taking the following medicines:

- Carbamazepine or phenytoin (anticonvulsants used to treat epilepsy),
- Rifampicin (an antibiotic),
- St. John's Wort (a herbal medicine used to treat depression),
- Hormone replacement therapy (HRT). Concomitant administration will make EQUISIN less effective.

EQUISIN with food and drink

The absorption of the active ingredient in EQUISIN is improved by food. Therefore, the tablet should be taken after a meal.

Pregnancy and breastfeeding

If you are pregnant, think you might be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking EQUISIN.

Do not take EQUISIN when you are pregnant or breastfeeding.

Driving and using machines

EQUISIN may make you sleepy, drowsy or dizzy. Do not drive or operate any tools or machines because your ability to perform these potentially hazardous tasks may be impaired.

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

EQUISIN contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium free".

3. How to take EQUISIN

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

Always take EQUISIN exactly as your doctor has or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and the elderly:

The usual dose is one EQUISIN 25 mg tablet daily.

- Take the tablet by mouth after a meal once a day, every day, at about the same time each day.
- Your doctor will tell you how long your treatment with EQUISIN will last. Do not stop treatment early even if you are feeling well, unless your doctor tells you.

If you have the impression that the effect of EQUISIN is too strong or too weak, tell your doctor or pharmacist.

Children:

EQUISIN is not suitable for use in children.

If you take more EQUISIN than you should

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

If you forget to take EQUISIN

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

If you forget to take your tablet, take it as soon as you remember. If it is nearly time for the next dose, take it at the usual time.

4. Possible side effects

EQUISIN can have side effects.

Not all side effects reported for EQUISIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking EQUISIN, please consult your doctor, pharmacist or

other healthcare provider for advice.

If any of the following happens, stop taking / using EQUISIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and 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 EQUISIN. You may need urgent medical attention or hospitalisation. Tell your doctor immediately or go to the casualty department at your nearest hospital.

Most of the side effects of EQUISIN are associated with a shortage of oestrogen (e.g., hot flushes).

Tell your doctor if you notice any of the following:

Frequent side effects:

- a reduction in the number of platelets in the blood, causing bruising and slow blood clotting
- a reduction in the number of white blood cells
- difficulty sleeping
- nausea
- headache
- hot flushes
- increased sweating
- loss of appetite
- pain, swollen hands and feet
- depression
- anxiety, feeling confused

- dizziness, carpal tunnel syndrome (a combination of pins and needles, numbness and pain affecting all of the hand except the little finger)
- high blood pressure
- swelling in an arm or leg caused by a lymphatic system blockage
- muscle and joint pain (including osteoarthritis, back pain, arthritis and joint stiffness)
- skin rash, hair loss
- stomach ache, vomiting, constipation, indigestion, diarrhoea
- hives
- thinning of bones which might decrease their strength (osteoporosis), leading to bone fractures (breaks or cracks) in some cases
- feeling of weakness
- tiredness
- elevated level of liver enzymes
- elevated level of a haemoglobin breakdown in the blood
- elevated level of a blood enzyme in the blood due to liver damage

Less frequent side effects:

- drowsiness
- inflammation of the liver
- inflammation of the bile ducts of the liver which cause yellowing of the skin
- a breakout of small blisters on an area of the skin in a rash

Side effects with unknown frequency:

- infection with bacteria, viruses, fungi, or parasites, in a host organism's body, leading to disease or illness of the respiratory tract, urine tract
- flu-like symptoms
- viral respiratory infection of the main airways of the lungs

- inflammation of the nasal passages, throat, runny nose

There may be changes in the amount of certain blood cells (lymphocytes) and platelets circulating in your blood, especially in patients with a pre-existing lymphopenia (reduced lymphocytes in the blood).

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 EQUISIN.

5. How to store EQUISIN

Store at or below 30 °C.

Store all medicines out of reach of children.

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

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

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 EQUISIN contains:

The active substance is exemestane. Each film-coated tablet contains 25 mg exemestane.

The other ingredients are copovidone type A, colloidal anhydrous silica, crospovidone type A, mannitol, magnesium stearate, microcrystalline cellulose, and sodium starch glycolate. The coating consists of hypromellose, macrogol 400 and titanium dioxide.

What EQUISIN looks like and contents of the pack

White to off-white, round compound cup film-coated tablet with “25” on one side and plain on the reverse.

PVC-PVdC/Aluminium blister strips with 10, 14, 20, 28, 30, 60 and 100 tablets per outer carton.

Holder of Certificate of Registration

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