SCHEDULING STATUS S4

PRODUCT NAME, STRENGTH AND PHARMACEUTICAL FORM ACCORD

LETROZOLE 2,5 mg. Tablets.

Each tablet contains 2,5 mg Letrozole.

Read all of this leaflet carefully before you start taking ACCORD LETROZOLE 2,5 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.
- **ACCORD LETROZOLE 2,5 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 **ACCORD LETROZOLE 2,5 mg** is and what it is used for
2. What you need to know before you use **ACCORD LETROZOLE 2,5 mg**
3. How to use **ACCORD LETROZOLE 2,5 mg**
4. Possible side effects
5. How to store **ACCORD LETROZOLE 2,5 mg**
6. Contents of the pack and other information

1. WHAT ACCORD LETROZOLE 2,5 mg IS USED FOR

ACCORD LETROZOLE 2,5 mg is used to treat breast cancer in women who have gone through menopause i.e cessation of periods.

It is used to prevent cancer from happening again. It can be used as first treatment before breast cancer surgery in case immediate surgery is not suitable or it can be used as first treatment after breast cancer surgery or following five years treatment with tamoxifen. **ACCORD LETROZOLE 2,5 mg** is also used to prevent breast tumour spreading to other parts of the body in patients with advanced breast cancer.

If you have any questions about how **ACCORD LETROZOLE 2,5 mg** works or why this medicine has been prescribed for you, ask your doctor.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ACCORD LETROZOLE 2,5 mg

Do not take ACCORD LETROZOLE 2,5 mg

- if you are (allergic) hypersensitive to letrozole or any of the other ingredients of **ACCORD LETROZOLE 2,5 mg** (see section 6.1).
- if you still have periods, i.e. if you have not yet gone through the menopause,
- if you are pregnant

  if you are breast-feeding
- if you have severe liver disease
- have severe kidney disease
- If you have a history of osteoporosis and/or fractures.

Warnings and precautions

Letrozole may cause inflammation in tendons or tendon injury (see section 4). At any sign of tendon pain or swelling – rest the painful area and contact your doctor.

Children and adolescents (below 18 years)

Children and adolescents should not use this medicine.

Older people (age 65 years and over)

People aged 65 years and over can use this medicine at the same dose as for other adults (see section 4.5).

Taking other medicines with ACCORD LETROZOLE 2,5 mg

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Pregnancy, breastfeeding and fertility:

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.

You should only take **ACCORD LETROZOLE 2,5 mg** when you have gone through the menopause. However, your doctor should discuss with you the use of effective contraception, as you may still have the potential to become pregnant during treatment with **ACCORD LETROZOLE 2,5 mg.**

You must not take **ACCORD LETROZOLE 2,5 mg** if you are pregnant or breast feeding as it may harm your baby.

Driving and using machinery:

It is not always possible to predict to what extent **ACCORD LETROZOLE 2,5 mg** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **ACCORD LETROZOLE 2,5 mg** affects them.

If you feel dizzy, tired, drowsy or generally unwell, do not drive or operate any tools or machines until you feel normal again.

ACCORD LETROZOLE 2,5 mg contains

ACCORD LETROZOLE 2,5 mg contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine

3. HOW TO TAKE ACCORD LETROZOLE 2,5 mg

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

Always take **ACCORD LETROZOLE 2,5 mg** exactly as your doctor told you. Check with your doctor or pharmacist if you are not sure.

The usual dose of **ACCORD LETROZOLE 2,5 mg** is one tablet once a day.

Taking **ACCORD LETROZOLE 2,5 mg** at the same time each day will help you remember when to take your tablet.

The tablet can be taken with or without food and should be swallowed whole with a glass of water or another liquid.

How long to take ACCORD LETROZOLE 2,5 mg

Continue taking **ACCORD LETROZOLE 2,5 mg** every day for as long as your doctor tells you. You may need to take it for months or even years. If you have any questions about how long to keep taking **ACCORD LETROZOLE 2,5 mg**, talk to your doctor.

Follow-up during ACCORD LETROZOLE 2,5 mg treatment

You should only take this medicine under strict medical supervision. Your doctor will regularly monitor your condition to check whether the treatment is having the right effect.

ACCORD LETROZOLE 2,5 mg may cause thinning or wasting of your bones (osteoporosis) due to the reduction of oestrogens in your body. Your doctor may decide to measure your bone density (a way of monitoring for osteoporosis) before, during and after treatment.

If you take more ACCORD LETROZOLE 2,5 mg than you should:

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

If you missed a dose of ACCORD LETROZOLE 2,5 mg:

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

4. POSSIBLE SIDE EFFECTS

ACCORD LETROZOLE 2,5 mg can have side effects.

Not all side effects reported for **ACCORD LETROZOLE 2,5 mg** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **ACCORD LETROZOLE 2,5 mg**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **ACCORD LETROZOLE 2,5 mg** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.

- Fainting.
- Rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **ACCORD LETROZOLE 2,5 mg**. You may need urgent medical attention or hospitalisation.

Most of the side effects are mild to moderate and will generally disappear after a few days to a few weeks of treatment.

Some of these side effects, such as hot flushes, hair loss or vaginal bleeding, may be due to the lack of oestrogens in your body.

The following side effects could be serious:

Frequent side effects:

- Hot flushes
- Increased level of cholesterol (hypercholesterolaemia)
- Fatigue
- Increased sweating
- Pain in bones and joints (arthralgia)
- Skin rash
- Headache
- Dizziness
- Malaise (generally feeling unwell)
- Gastrointestinal disorders such as nausea, vomiting, indigestion, constipation, diarrhoea
- Increase in or loss of appetite
- Pain in muscles
- Thinning or wasting of your bones (osteoporosis), leading to bone fractures in some cases (see also

- “Follow-up during Femara treatment” in section 3)
- Swelling of arms, hands, feet, ankles (oedema)
- Depression
- Weight increase
- Hair loss
- Raised blood pressure (hypertension)
- Abdominal pain
- Dry skin
- Vaginal bleeding
- Palpitations, rapid heart rate
- Joint stiffness (arthritis)
- Chest pain

Less frequent side effects:

- Weakness, paralysis or loss of feeling in any part of the body (particularly arm or leg), loss of coordination, nausea, or difficulty speaking or breathing (sign of a brain disorder, e.g. stroke).
- Sudden oppressive chest pain (sign of a heart disorder).
- Swelling and redness along a vein which is extremely tender and possibly painful when touched.
- Severe fever, chills or mouth ulcers due to infections (lack of white blood cells).
- Severe persistent blurred vision.
- Inflammation of a tendon or tendonitis (connective tissues that connect muscles to bones).

- Difficulty breathing, chest pain, fainting, rapid heart rate, bluish skin discoloration, or sudden arm, leg or foot pain (signs that a blood clot may have formed).
- Rupture of a tendon (connective tissues that connect muscles to bones) Nervous disorders such as anxiety, nervousness, irritability, drowsiness, memory problems, somnolence, insomnia
- Pain or burning sensation in the hands or wrist (carpal tunnel syndrome)
- Impairment of sensation, especially that of touch
- Eye disorders such as blurred vision, eye irritation
- Skin disorders such as itching (urticaria)
- Vaginal discharge or dryness
- Breast pain
- Fever
- Thirst, taste disorder, dry mouth
- Dryness of mucous membranes
- Weight decrease
- Urinary tract infection, increased frequency of urination
- Cough
- Increased level of enzymes
- Yellowing of the skin and eyes
- High blood levels of bilirubin (a breakdown product of red blood cells)

Side effects with frequency not known (frequency cannot be estimated from the available data)

- Trigger finger, a condition in which your finger or thumb catches in 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 or pharmacist. 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 **ACCORD LETROZOLE 2,5 mg**.

5. HOW TO STORE ACCORD LETROZOLE 2,5 mg.

- Store below 25 °C.
- Do not remove the blisters from the outer container until required for use.
- **KEEP OUT OF THE 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 ACCORD LETROZOLE 2,5 mg contains

The active substance is letrozole.

The other ingredients are**:**

Tablet core:

Cellulose microcrystalline, colloidal anhydrous silica, hypromellose Type 2910, lactose monohydrate, magnesium stearate, maize starch

sodium starch glycolate Type A

Coating (Opadry 03B82927 yellow):

Hypromellose 6 cp E464, macrogol 400, iron oxide yellow E172, talc E553b,

titanium dioxide E171

What ACCORD LETROZOLE 2,5 mg looks like and contents of the pack

ACCORD LETROZOLE 2,5 mg are yellow, round, biconvex, film coated tablets, plain on both sides.

ACCORD LETROZOLE 2,5 mg film coated tablets are packed in plain aluminium blister strips of 10 tablets per strip, with a clear PVC coated PVDC film.

3 strips of 10 tablets (30 tablets) are packed in a unit carton.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Detailed information on this medicinal product is available

medinfo@accordhealth.co.za.