AMENDED PROPOSED PATIENT INFORMATION LEAFLET (CLEAN COPY)

SCHEDULING STATUS

S4

Accord Anastrozole (film coated tablet)

Anastrozole

Contains sugar: 95,25 mg lactose monohydrate per tablet

Read all of this leaflet carefully before you start taking Accord Anastrozole

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **Accord Anastrozole** 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 ANASTROZOLE is and what it is used for
2. What you need to know before you take ACCORD ANASTROZOLE
3. How to take ACCORD ANASTROZOLE
4. Possible side effects
5. How to store ACCORD ANASTROZOLE
6. Contents of the pack and other information

1. WHAT ACCORD ANASTROZOLE IS AND WHAT IT IS USED FOR

Accord Anastrozole contains a medicine called anastrozole. This belongs to a group of medicines called 'aromatase inhibitors'. **Accord Anastrozole** is used to treat breast cancer in women who have gone through the menopause. **Accord 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'.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ACCORD ANASTROZOLE

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Do not take ACCORD ANASTROZOLE:

- if you are allergic (hypersensitive) to anastrozole or any of the other ingredients of Accord Anastrozole (see **WHAT ACCORD ANASTROZOLE CONTAINS**), listed in section 6.
- If you still have menstrual periods and have not yet gone through the menopause.
- if you have moderate or severe liver problems.
- if you have severe kidney problems.
- if you are taking a medicine called tamoxifen or medicines that contain oestrogen.
- if you are pregnant or breastfeeding.

Do not take **Accord Anastrozole** if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking **Accord Anastrozole**.

Warnings and precautions

Take special care with Accord Anastrozole:

Check with your doctor or pharmacist before taking **Accord Anastrozole** if:

- you have ever had a condition that affects the strength of your bones (osteoporosis or osteopenia).
- you have problems with your liver or kidneys.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Accord Anastrozole.

If you go into hospital, let the medical staff know you are taking Accord Anastrozole.

Effects on your bones

Accord Anastrozole lowers the amount of the hormone called oestrogen that is in your body. This may lower the mineral content of your bones. Your bones may be less strong and may be more likely to fracture. Your doctor will manage these risks. You should talk to your doctor about the risks and treatment options.

Children and adolescents

Accord Anastrozole should not be given to children.

Other medicines and ACCORD ANASTROZOLE

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

This is because Accord Anastrozole can affect the way some medicines work and some medicines can have an effect on Accord Anastrozole.

Pregnancy and breastfeeding:

Do not take Accord Anastrozole if you are pregnant 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 healthcare professional for advice before taking Accord Anastrozole.

Driving and using machines:

Some people may occasionally feel weak, dizzy or sleepy while taking Accord Anastrozole. This may affect your ability to drive or use machinery. If this happens to you, ask your doctor or pharmacist for advice.

It is not always possible to predict to what extent ACCORD ANASTROZOLE 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 ACCORD ANASTROZOLE affects you.

Accord Anastrozole contains lactose monohydrate:

Accord Anastrozole contains lactose which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have intolerance to some sugars), talk to your doctor before taking Accord Anastrozole.

3. HOW TO TAKE ACCORD ANASTROZOLE:

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

Always take Accord Anastrozole exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Accord Anastrozole should not be given to children.

- The usual dose is one tablet once a day.
- Try to take your tablet at the same time each day.

- Swallow the tablet whole with a drink of water.
- It does not matter if you take Accord Anastrozole before, with or after food.

Keep taking Accord Anastrozole for as long as your doctor tells you to, It is a long-term treatment and you may need to take it for several years.

If you take more Accord Anastrozole 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 forget to take Accord Anastrozole:

If you forget to take a dose, just take your next dose as normal.

Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking Accord Anastrozole:

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

4. POSSIBLE SIDE EFFECTS:

Accord Anastrozole can have side effects.

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

Serious allergic reactions

If any of the following happen to you, call an ambulance or see a doctor straight away – you may have had a serious reaction to ACCORD ANASTROZOLE and you may need urgent medical treatment:

- Swelling of the face, lips, tongue or throat. This may cause difficulty in swallowing or breathing
- An extremely severe skin reaction with ulcers or blisters on the skin- This is known as 'Stevens-Johnson syndrome

Liver effects

The signs may include:

- Yellowing of your skin or eyes, dark coloured urine, a loss of appetite and a general feeling of being unwell.

If this happens to you, see a doctor straight away, you may need medical tests or treatment.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Hot flushes, fluid retention which causes swollen hands, ankles or feet.
- Feeling depressed
- Feeling weak.
- Pain or stiffness in your joints.
- Skin rash (this can include a type of rash called 'hives' or 'nettle rash').
- Feeling sick (nausea).
- Headache, dizziness.
- Tingling or numbness in your hands and feet, loss of taste or changes in taste
- Vaginal dryness.
- Bleeding from the vagina (usually in the first few weeks of treatment - if the bleeding continues, talk to your doctor).
- Thinning of your hair (hair loss).
- 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.
- Being sick (vomiting).
- 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:

- Trigger finger (a condition in which your finger or thumb catches in a bent position).
- Feeling sleepy

Frequency unknown:

- Low levels of white blood cells which may result in infections – you may experience fever, chills, sore throat.
- Blood clot in the veins which causes pain and inflammation – you may experience redness, swelling, tenderness, or warmth of the affected area.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety App (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of **ACCORD ANASTROZOLE.**

5. HOW TO STORE ACCORD ANASTROZOLE:

Store at or below 25 °C. Do not remove from outer container until required for use.

Do not take your tablets after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENT OF THE PACK AND OTHER INFORMATION

What ACCORD ANASTROZOLE contains:

- The active substance is anastrozole.
- The other ingredients are lactose monohydrate, Povidone K-30, sodium starch glycolate and magnesium stearate.
- The film coating contains hydroxypropyl methyl cellulose, Macrogol 300 and titanium dioxide

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What ACCORD ANASTROZOLE looks like and contents of the pack

ACCORD ANASTROZOLE tablets are white to off white, round, biconvex, film coated tablets with 'AHI' debossing on one side and plain on other side.

Accord Anastrozole tablets are packaged in a plain aluminium blister foil with a clear PVC film coated PVDC. There are 3 blister strips of 10 tablets each, packed into an outer cardboard box as a pack size of 30 tablets.

HOLDER OF CERTIFICATE OF REGISTRATION

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