Applicant : Eurolab (Pty) Ltd
Proprietary name : Stradexa
Dosage form and strength : Film-coated tablet 1 mg
Date of submission : 07 April 2021
Approval date : 07 May 2021

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S4**

STRADEXA 1 mg film coated tablet

anastrozole

Contains sugar: 95,250 lactose monohydrate

Read all of this leaflet carefully before you start taking Stradexa

- 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.
- **Stradexa** 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 **STRADEXA** is and what it is used for
2. What you need to know before you take **STRADEXA**
3. How to take **STRADEXA**
4. Possible side effects
5. How to store **STRADEXA**
6. Contents of the pack and other information

1. What STRADEXA is and what it is used for

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

Do not take STRADEXA

- if you are hypersensitive (allergic) to anastrozole or any of the other ingredients of **Stradexa** (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 **Stradexa** if any of the above apply to you. If you are not talk to your doctor or pharmacist before taking **Stradexa**.

Stradexa should not be given to children.

Warnings and precautions

Take special care with **Stradexa**

- 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 are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking **Stradexa**.

If you go into hospital, let the medical staff know you are taking **Stradexa**.

Other medicines and STRADEXA

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

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

Pregnancy, breastfeeding and fertility

Do not take **Stradexa** 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 health care provider for advice before taking **Stradexa**.

Driving and using machines

However, some people may occasionally feel weak, dizzy or sleepy while taking **Stradexa**. If this happens to you, ask your doctor or pharmacist for advice.

Stradexa contains lactose

Stradexa 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 **Stradexa**.

3. How to take STRADEXA

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

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

Stradexa 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 **Stradexa** before, with or after food.

Keep taking **Stradexa** 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 Stradexa 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 Stradexa

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 Stradexa

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

4. Possible side effects

Stradexa can have side effects.

Not all side effects reported for **Stradexa** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **Stradexa**, please consult your health care provider for advice.

Serious allergic reactions

If any of the following happen to you, call an ambulance or see a doctor straight away – 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.

Other possible side effects:

Frequent:

- Hot flushes.
- 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.
- 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).
- Feeling sleepy.
- 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).
- Depression.

Effects on your bones

Stradexa 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. 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 or, 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 **Stradexa**.

5. How to store STRADEXA

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. Contents of the pack and other information

What **Stradexa** contains

The active substance is 1 mg of anastrozole.

The other ingredients in **Stradexa** tablets are: lactose monohydrate, magnesium stearate, hydroxypropylmethylcellulose, polyethylene glycol, povidone, sodium starch glycolate, and titanium dioxide.

What Stradexa looks like and contents of the pack

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

Stradexa 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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Gauteng

South Africa

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