1.3.2 Patient Information Leaflet

SCHEDULING STATUS

S4

PATIENT INFORMATION LEAFLET

CABREXID film-coated tablets

(Anastrozole)

(Contains Sugar: Lactose monohydrate)

Read all of this leaflet carefully before you take CABREXID

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist, nurse or other health care provider.
- **CABREXID** 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:

15-Mar-2023

1. What CABREXID is and what it is used for

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

CABREXID 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 CABREXID

Do not take CABREXID:

- If you are hypersensitive (allergic) to anastrozole or any of the ingredients of **CABREXID** (listed in section 6).
- If you are pregnant or breast-feeding
- If you are pre-menopausal (still have menstrual periods)
- If you have severe kidney disease
- If you have moderate or severe liver disease

If you are not sure, talk to your doctor or pharmacist before taking **CABREXID**.

Warnings and precautions

Tell your doctor, pharmacist or healthcare professional before taking **CABREXID**:

- if you still have menstrual periods and have not yet gone through the menopause.

- if you are taking a medicine that contains tamoxifen or medicines that contain oestrogen (see 'Other medicines and **CABREXID**').
- 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 being given this medicine.

Children and adolescents

CABREXID has not been studied in children or adolescents and therefore should not be used in this patient population.

Other medicine and CABREXID:

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

The use of **CABREXID** with these medicines may cause undesirable interactions.

In particular tell your doctor if you are taking:

- Certain medicines used to treat breast cancer, e.g. medicines that contain tamoxifen. This is because these medicines may stop **CABREXID** from working properly.
- Medicines that contain oestrogen, such as hormone replacement therapy (HRT).

Pregnancy, breastfeeding and fertility

Do not take **CABREXID** 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 provider for advice before taking this medicine.

Stop taking **CABREXID** if you become pregnant and talk to your doctor.

Driving and using machines

Some people may feel weak or sleepy while taking **CABREXID**.

Do not drive or operate tools or machines if you experience such side effects.

It is not always possible to predict to what extent **CABREXID** 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 **CABREXID** affects you.

CABREXID contains sugar

CABREXID contains lactose monohydrate which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **CABREXID**.

3. How to take CABREXID

Do not share medicines prescribed for you with any other person. Always take **CABREXID** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is one tablet of **CABREXID** once a day.

Your doctor will tell you how long your treatment with **CABREXID** will last. Do not stop any treatment unless your doctor tells you to do so.

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

If you take more CABREXID 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 CABREXID

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

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

If you stop taking CABREXID

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

4. Possible side effects

CABREXID can have side effects.

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

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

- Swelling around the eyes or face, tongue or throat, (which may be a serious allergic reaction)
- An extremely severe skin reaction with ulcers or blisters on the skin (this is known as ‘Stevens-Johnson syndrome’).

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

Treatment with **CABREXID** can cause:

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- Headache
- Hot flushes
- Feeling sick (nausea)
- Skin rash
- Pain or stiffness in your joints
- Inflammation of the joints (arthritis)
- Feeling weak

Tell your doctor if you notice any of the following:

Frequent side effects:

- Loss of appetite
- Feeling sleepy
- Carpal tunnel syndrome (tingling, pain, coldness, weakness in parts of the hand)
- Tickling, tingling or numbness of skin, loss/lack of taste
- Diarrhoea
- Being sick (vomiting)
- Changes in blood tests that show how well your liver is working
- Thinning of your hair (hair loss)
- Bone pain
- Muscle pain and weakness
- Vaginal dryness
- Bleeding from the vagina (usually in the first few weeks of treatment – if the bleeding continues, talk to your doctor)

Less frequent side effects:

- Changes liver function tests
- Raised or high levels of fatty substance known as cholesterol in your blood. This would be seen in a blood test
- Inflammation of the liver (hepatitis)
- Hives or nettle rash
- Trigger finger (a condition in which your finger or thumb stays in a bent position)
- Increased amounts of calcium in your blood. If you experience nausea, vomiting and thirst, you should tell your doctor, or pharmacist or nurse as you may need to have blood tests
- Inflammation of your skin that may include red patches or blisters
- Skin rash caused by hypersensitivity (this can be from allergic or anaphylactoid reaction)
- Inflammation of the small blood vessels causing red or purple colouring of the skin. Symptoms of joint, stomach, and kidney pain may occur; this is known as 'HenochSchönlein purpura'.

Effects on your bones

CABREXID 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 according to treatment guidelines for managing bone health in women who have gone through the menopause. You should talk to your doctor about the risks and treatment options.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects via https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **CABREXID**.

5. How to store CABREXID

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

CABREXID will be stored in the pharmacy

Store at or below 25 °C.

Keep the container in the outer carton in order to protect from light.

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

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 CABREXID contains

The active substance is anastrozole.

Each film-coated tablet contains 1 mg anastrozole.

Contains sugar: lactose monohydrate 91,00 mg.

The other ingredients of **CABREXID** are: Lactose monohydrate, sodium starch glycolate, Povidone K-30, magnesium stearate.

Coating material: MPMC 2910/Hypromellose, titanium dioxide (CI 77891),

Macrogol/PEG

What CABREXID looks like and contents of the pack

CABREXID is a white, biconvex, film-coated tablet debossed with ‘A1’ on one side and plain on the other side.

CABREXID is supplied in pre-printed cartons containing 30 tablets in 25 micron aluminium foil / clear 25 micron PVC film blister packs. Each carton contains 3 blisters of 10 film-coated tablets each and a leaflet.

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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