# PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS: S5**

**CABREXXA® 0,5; 0,5 mg film-coated tablets**

**CABREXXA® 1; 1 mg film-coated tablets**

**Varenicline tartrate**

Sugar free

## Read all of this leaflet carefully before you start taking CABREXXA

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

CABREXXA contains the active substance varenicline tartrate. CABREXXA is a medicine which is used in adults to help them stop smoking. CABREXXA can help to relieve the craving and withdrawal symptoms associated with stopping smoking. CABREXXA can also reduce the enjoyment of cigarettes if you do smoke when on treatment.

## 2. What you need to know before you take CABREXXA

### Do not take CABREXXA:

- if you are hypersensitive (allergic) to varenicline tartrate or any of the other ingredients of CABREXXA (listed in section 6).

### Warnings and precautions

*Take special care with CABREXXA:*

- if you are taking other medicines (see “Other medicines and CABREXXA”).
- Tell your doctor if you have kidney problems. Your doctor may prescribe a lower dose of CABREXXA for you.
- Tell your doctor if you have an existing heart condition.

  New or worse heart or blood vessel (cardiovascular) problems have been reported primarily in people who already have cardiovascular problems. Tell your doctor if you have any changes in symptoms during treatment with CABREXXA. Get emergency medical help right away if you have symptoms of a heart attack or stroke.
- Tell your doctor if you have depression or other mental health problems (e.g. schizophrenia, bipolar disorder).

There have been reports of depression, suicidal ideation and behaviour and suicide attempts in patients taking CABREXXA. If you are taking CABREXXA and develop agitation, depressed mood, changes in behaviour that are of concern to you or your family, or if you develop suicidal thoughts or behaviour, you should stop taking CABREXXA and contact your doctor immediately for treatment assessment.

*The effects of stopping smoking*

The effects of changes in your body resulting from stopping smoking, with or without treatment with CABREXXA, may alter the way other medicines work. Therefore, in some cases an adjustment of the dose may be necessary. Tell your doctor if you take other medicines; see 'Other medicines and CABREXXA' for further details.

For some people, stopping smoking with or without treatment has been associated with an increased risk of experiencing changes in thinking or behaviour, feelings of depression and anxiety and can be associated with a worsening of psychiatric disorder. If you have a history of psychiatric disorder, you should discuss this with your doctor.

*Seizures*

Tell your doctor if you have experienced seizures or have epilepsy before you start CABREXXA treatment. Some people have reported seizures while taking CABREXXA.

*Children and adolescents*

CABREXXA is not recommended for use in paediatric patients as efficacy was not demonstrated.

## Other medicines and CABREXXA

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

In some cases, as a result of stopping smoking, with or without CABREXXA, an adjustment of the dose of other medicines may be necessary. Examples include:

- theophylline (a medicine to treat breathing problems),

- warfarin (a medicine to reduce blood clotting),
- insulin, metformin (medicines to treat diabetes),
- digoxin (a medicine for heart problems),
- cimetidine: If you have severe kidney disease you should avoid taking cimetidine (a medicine used for gastric problems) at the same time as CABREXXA as this may cause increased blood levels of CABREXXA.

*Use of CABREXXA with other therapies for smoking cessation*

Consult your doctor before using CABREXXA in combination with other smoking cessation therapies, for example bupropion, nicotine replacement patches.

## CABREXXA with food and drink

CABREXXA can be taken with or without food.

There have been some reports of increased intoxicating effects of alcohol in patients taking CABREXXA.

## Pregnancy and 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 CABREXXA.

*Pregnancy:*

You should not take CABREXXA while you are pregnant.

If you are pregnant or planning to become pregnant, you should try to stop smoking. Stopping smoking has benefits for both you and the health of your baby. Talk to your doctor if you are intending to become pregnant. If you want to start treatment with CABREXXA, your treatment should be timed so that you have completed the course before becoming pregnant.

*Breastfeeding:*

Women taking CABREXXA should not breastfeed their babies. The safety of CABREXXA during lactation has not been established.

## Driving and using machines

CABREXXA may be linked with dizziness, sleepiness and transient loss of consciousness. You should not drive, operate complex machinery or engage in any other potentially hazardous activities until you know whether this medicine affects your ability to perform these activities.

## 3. How to take CABREXXA

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

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

You are more likely to stop smoking if you are motivated to stop.

Your doctor and pharmacist can provide advice, support and sources of further information to help ensure your attempt to stop smoking is successful.

Before starting your course of CABREXXA you should usually decide on a date in the second week of treatment (between day 8 and day 14) when you will stop smoking. If you are not willing or able to set a target quit date within 2 weeks, you may choose your own target quit date within 5 weeks after starting treatment. You should write this date on the pack as a reminder.

CABREXXA comes as a white tablet (0,5 mg) and a light blue tablet (1 mg). You start with the white tablet and then usually go to the light blue tablet.

See the chart below for the usual dosing instructions which you should follow from Day 1.

| Week 1 | Dose |
|---|---|
| Day 1 - 3 | Take one white CABREXXA 0,5 film-coated tablet once a day in the evening. |
| Day 4 - 7 | Take one white CABREXXA 0,5 film-coated tablet twice daily, once in the morning and once in the evening, at about the same time each day. |
| Week 2 | |
| Day 8 to end of treatment | Take one light blue CABREXXA 1 film-coated tablet twice daily, once in the morning and once in the evening, at about the same time each day. |

After 12 weeks of treatment, if you have stopped smoking, your doctor may recommend an additional 12 weeks of treatment with CABREXXA 1 mg film-coated tablets twice daily to help avoid smoking again.

Should you experience adverse effects that you cannot tolerate your doctor may decide to reduce your dose.

If you have problems with your kidneys, you should speak to your doctor before taking CABREXXA. You may need a lower dose.

CABREXXA is for oral use. The tablets should be swallowed whole with water and can be taken with or without food.

## If you take more CABREXXA 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 your box of tablets with you.

## If you forget to take CABREXXA

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

It is important that you take CABREXXA regularly at the same time each day. If you forget to take a dose, take it as soon as you remember. If it is within 3-4 hours before your next dose, do not take the tablet that you have missed.

### If you stop taking CABREXXA

Taking all doses of your medicine at the appropriate times and for the recommended duration of treatment described above will increase your chances of stopping smoking. Therefore, unless your doctor instructs you to stop treatment, it is important to keep taking CABREXXA, according to the instructions described above.

In smoking cessation therapy, risk of returning to smoking may be higher in the period just after ending the treatment. You may temporarily experience increased irritability, urge to smoke, depression and/or sleep disturbances when you stop taking CABREXXA. Your doctor may decide to gradually lower your dose of CABREXXA at the end of treatment.

If you have any further questions on the use of CABREXXA, ask your doctor or pharmacist.

## 4. Possible side effects

CABREXXA can have side effects.

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

### If any of the following happens, stop taking CABREXXA 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 (angioedema),

- severe skin rashes including erythema multiforme (red or pink blotches, sometimes with blisters) and Stevens-Johnson syndrome (a serious reaction with blistering of the skin, mouth, around the eyes or genitals).

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

**Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:**

- angina (chest pain), irregular or fast heartbeat (heart rhythm disturbances), palpitations, heart attack,
- stroke (sudden numbness or weakness in the face, arm or leg, sudden confusion, difficulty with speech, difficulty with coordination).

These are all serious side effects. You may need urgent medical attention.

**Tell your doctor if you notice any of the following:**

*Frequent side effects:*

- inflammation of the nose, throat and sinuses,
- chest infection,
- increased weight,
- decreased appetite or increased appetite,
- abnormal dreams,
- difficulty sleeping,
- headache,
- drowsiness,
- changes in the way things taste,
- shortness of breath, cough,

- nausea, vomiting,
- acid reflux,
- constipation, feeling bloated,
- toothache,
- abdominal pain, indigestion, flatulence,
- dry mouth,
- skin rash, itching,
- joint ache, muscle ache, back pain,
- chest pain,
- fatigue,
- abnormal liver function tests (shown with laboratory tests).

*Less frequent side effects:*

- recurrent viral or fungal infections,
- decrease in blood platelets,
- high blood sugar, excessive thirst, diabetes,
- suicidal thoughts (see “Take special care with CABREXXA”), changes in thinking or behaviour (such as aggression), feeling of panic, difficulty thinking, restlessness, mood swings, depression, anxiety, hallucinations,
- changes in sex drive,
- loss of contact with reality and unable to think or judge clearly (psychosis),
- sleep walking,
- abnormal behaviour, melancholy, slowed thinking,
- seizure, tremor, feeling sluggish, less sensitive to touch,
- sleep disorders,
- conjunctivitis (inflammation/infection of the eye), eye pain,

- disturbed vision, eyeball discolouration, dilated pupils, sensitivity to light, shortsightedness, watery eyes,
- ringing in the ears,
- increased blood pressure, hot flush,
- congestion of nose, throat and chest, hoarseness, hay fever, throat irritation, congested sinuses, excess mucus from nose causing cough, runny nose,
- throat pain, snoring,
- red blood in stools, irritated stomach, change of bowel habit, belching, mouth ulcers, pain in the gums,
- blood in vomit, abnormal stools, coated tongue,
- reddening of the skin, acne, increased sweating, night sweats,
- muscle spasms, chest wall pain,
- stiff joints, rib pain,
- abnormal frequent urination, high volumes of urine, urination at night,
- glucose in urine,
- increased menstrual flow,
- vaginal discharge, changes in sexual ability,
- chest discomfort, flu like illness, fever, feeling weak or unwell,
- feeling cold, cyst.

*Frequency not known*

- Transient loss of consciousness.

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 CABREXXA.

## 5. How to store CABREXXA

Store all medicines out of reach of children.

Blisters: Store at or below 25 °C.

Do not use this medicine after the expiry date which is stated on the card packaging or carton after EXP. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

These measures will help protect the environment.

## 6. Contents of the pack and other information

### What CABREXXA contains

- The active substance is varenicline.

Each 0,5 mg film-coated tablet contains 0,5 mg of varenicline (as tartrate). Each 1 mg film-coated tablet contains 1 mg of varenicline (as tartrate).

- The other ingredients are:

Tablet core: Croscarmellose sodium, maltodextrin, microcrystalline cellulose, stearic acid.

Tablet film coating CABREXXA 0,5: Hydroxypropyl cellulose, hypromellose, talc, titanium dioxide (E171).

Tablet film coating CABREXXA 1 mg: FD&C Blue #2/indigo carmine aluminium lake (E132), hydroxypropyl cellulose, hypromellose, talc, titanium dioxide (E171).

## What CABREXXA looks like and contents of the pack

Film-coated tablets.

CABREXXA 0,5 mg: White to off-white, capsular shaped, biconvex film-coated tablets debossed with “C2” on one side and plain on other side.

CABREXXA 1,0 mg: Light blue, capsular shaped, biconvex film-coated tablets debossed with “C1” on one side and plain on other side.

CABREXXA is available in blister strips of transparent PVC Armour film with silver aluminium foil lidding, packed in printed folding carton.

Pack sizes:

Starter (initial dosing) pack containing 2 blister strips: one blister strip of 11 x CABREXXA 0,5 film-coated tablets and one blister strip of 14 x CABREXXA 1 film-coated tablets.

Starter (initial dosing) pack containing 4 blister strips: one blister strip of 11 x CABREXXA 0,5 film-coated tablets and three blister strips of 14 x CABREXXA 1 film-coated tablets.

Follow-on (maintenance) pack: two or four blister strips of 14 x CABREXXA 1 film-coated tablets.

Not all pack sizes may be marketed.

## Holder of Certificate of Registration

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## This leaflet was last revised

23 May 2023

## Registration numbers

CABREXXA 0,5: 55/2.11/0517.515

CABREXXA 1: 55/2.11/0518.516