PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

RAVOQUIX 0,5 mg Film-coated tablets

RAVOQUIX 1 mg Film-coated tablets

Varenicline tartrate

Sugar free

Read all of this leaflet carefully before you start taking RAVOQUIX

- 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.
- RAVOQUIX 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 RAVOQUIX is and what it is used for

RAVOQUIX is a medicine used to help you stop smoking, in addition to a behavioural modification programme.

RAVOQUIX can help to relieve the craving and withdrawal symptoms associated with stopping smoking.

It is recommended that you do not smoke while taking RAVOQUIX

2. What you need to know before you take RAVOQUIX

RAVOQUIX should not be administered to you:

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

Warnings and precautions with RAVOQUIX

Tell your doctor or health care provider before taking RAVOQUIX:

Take special care should be taken with RAVOQUIX:

- If you have kidney problems. Your doctor may prescribe a lower dose of RAVOQUIX for you.
- If you have experienced 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 RAVOQUIX. If you are taking RAVOQUIX and develop agitation, depressed mood, changes in behaviour that are of concern to you or your family or if you develop suicidal thoughts or behaviours you should stop taking RAVOQUIX and contact your doctor immediately for treatment assessment.
- If you have a history of seizures (fits). Some people have reported seizures while taking RAVOQUIX.
- If you experience any of the following signs and symptoms that may indicate a serious allergic reaction: swelling of the face, lips, tongue, gums, throat or body and/or difficulty breathing, wheezing. Stop taking RAVOQUIX and tell your doctor immediately.
- If you develop a rash or if your skin starts to peel or blister you should stop taking RAVOQUIX and seek emergency medical help. Potentially life-threatening skin rashes (Stevens-Johnson syndrome and Erythema Multiforme) have been reported with the use of RAVOQUIX.
- If you have an existing heart condition, tell your doctor. 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 RAVOQUIX. Get emergency medical help right away if you have symptoms of a heart attack or stroke.

- If you are pregnant or plan to become pregnant. RAVOQUIX has not been studied in pregnant women. It is not known if RAVOQUIX will harm your unborn baby. It is best to stop smoking before you get pregnant.
- If you are breastfeeding. Although it was not studied in humans, RAVOQUIX may pass into breastmilk.

The effects of stopping smoking

The effects of changes in your body resulting from stopping smoking, with or without treatment with RAVOQUIX, may alter the way other medicines work. Therefore, in some cases an adjustment of the dose may be necessary. Examples include theophylline (a medicine to treat breathing problems), warfarin (a medicine to reduce blood clotting), and insulin (and other antidiabetic medicines to treat diabetes). If in doubt, you should consult your doctor or pharmacist.

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.

Heart symptoms

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 RAVOQUIX. Get emergency medical help right away if you have symptoms of a heart attack or stroke.

Seizures

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

Hypersensitivity reactions

Stop taking RAVOQUIX and tell your doctor immediately if you experience any of the following signs and symptoms that may indicate a serious allergic reaction: swelling of the face, lips, tongue, gums, throat or body and/or difficulty breathing, wheezing.

Skin reactions

Potentially life-threatening skin rashes (Stevens-Johnson syndrome and Erythema Multiforme) have been reported with the use of RAVOQUIX. If you develop a rash or if your skin starts to peel or blister you should stop taking RAVOQUIX and seek emergency medical help.

Taking other medicines and RAVOQUIX:

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

Tell your doctor if you take:

- Asthma medicines (e.g. theophylline)
- Insulin or other antidiabetic medicines
- Blood-thinning medicines (e.g. warfarin)
- Gastrointestinal medicines (e.g. cimetidine)

Taking RAVOQUIX with food and drink

RAVOQUIX can be taken with or without food.

There have been some reports of increased intoxicating effects of alcohol in patients taking RAVOQUIX. You should reduce the amount of alcohol consumed while taking RAVOQUIX. until it is known whether it affects your tolerance for alcohol.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, 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 not take RAVOQUIX while you are pregnant.

If you are pregnant or are 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 RAVOQUIX, your treatment should be timed so that you have completed the course before becoming pregnant.

Although it was not studied in humans, RAVOQUIX may pass into breastmilk.

Women taking RAVOQUIX should not breastfeed their infants.

Driving and using machines

RAVOQUIX may make you feel 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 RAVOQUIX

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

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

How much to take or give

Choose the date to stop smoking. Start taking RAVOQUIX 1 - 2 weeks before this date. You can keep smoking during this time.

You should be treated with RAVOQUIX for 12 weeks.

The recommended dose of RAVOQUIX is 1 mg twice daily following a 1-week titration as follows:

Day 1 -3:	0,5 mg once daily in the evening
Day 4 -7	0,5 mg twice daily
Day 8 -End of treatment:	1 mg twice daily

If you do not stop smoking during the first 12 weeks of treatment or if you start smoking again after treatment, you can make another attempt at stopping smoking. However, before you make another attempt, you should try to understand the reasons why your attempt to stop smoking failed, so that your next attempt has a better chance of success.

If you are not able or willing to quit smoking straight away, you should reduce smoking during the first 12 weeks of treatment and quit by the end of that treatment period. You should then continue to take RAVOQUIX for a further 12 weeks resulting in a total of 24 weeks of treatment.

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

If you have problems with your kidneys, you should speak to your doctor before taking RAVOQUIX.

RAVOQUIX is not recommended for use in children under 18 years.

If you take more RAVOQUIX 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 use RAVOQUIX

Do not take a double dose to make up for a forgotten individual doses. It is important that you take RAVOQUIX regularly at the same time each day. If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the tablet that you have missed.

4. Possible side effects

RAVOQUIX can have side effects

Not all side effects reported for RAVOQUIX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RAVOQUIX, please consult your health care provider for advice.

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

- Itching or a rash

- Difficulty breathing

These are all very serious side effects. If you have them, you may have had a serious reaction to RAVOQUIX. 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:

- Increased heart rate
- Abnormal heart rhythm
- Chest pain
- Feeling weak or unwell

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 nasal passages and sinuses
- Abnormal dreams
- Difficulty sleeping
- Headache
- Nausea
- Inflammation of the air passages (bronchitis)
- Inflammation of the sinuses
- Increased weight
- Loss of appetite
- Increased appetite
- Sleepiness
- Dizziness
- Changes in the way things taste
- Tremors
- Lack of energy
- Tight muscles

- Slurred speech
- Abnormal coordination
- Difficulty breathing
- Cough
- Heartburn
- Vomiting
- Constipation
- Diarrhoea
- Feeling bloated
- Abdominal pain
- Toothache
- Indigestion
- Flatulence
- Dry mouth
- Stomach discomfort
- Joint ache
- Muscle ache
- Skin rash
- Itching
- Joint pain
- Muscle pain
- Back pain
- Chest pain
- Tiredness
- Abnormal liver laboratory tests

Less frequent side effects

- Fungal infection
- Viral infection

- Decreased blood cell count
- Loss of appetite
- Feeling thirsty
- Feeling of panic
- Difficulty thinking
- Mood swings
- Changes in sex drive
- General uneasy feeling
- Restlessness
- Reduced sense of taste
- Changes in sleep patterns
- Chest pain
- Palpitations
- Increased heart rate
- Abnormal heart rhythm
- Abnormal electrocardiogram
- Increased blood pressure
- Hot flushes
- Inflammation of the eye
- Eye pain
- Disturbed vision
- Eyeball discolouration
- Dilated pupils
- Sensitivity to light
- Short-sightedness
- Watery eyes
- Ringing in the ears
- Inflammation of nose, sinuses and throat
- Congestion

- Difficulty in speaking
- Runny nose
- Throat irritation
- Congested sinuses
- Hoarseness
- Throat pain
- Snoring
- Postnasal drip
- Red blood in stools
- Irritated stomach
- Change in bowel habits
- Burping
- Mouth ulcers
- Pain in the gums
- Blood in vomit
- Abnormal stools
- Coated tongue
- Reddening of the skin
- Acne
- Increased sweating
- Sweating at night
- Muscle spasms
- Chest wall and rib pain
- Stiff joints
- Inflammation of the cartilage in the rib cage
- Frequent daytime urination (passing water)
- Increased urination at night
- Glucose in urine
- Increased urine volume

- Increased menstrual flow
- Vaginal discharge
- Changes in sexual function
- Chest discomfort
- Flu-like illness
- Fever
- Feeling weak or unwell
- Feeling cold
- Cysts
- Abnormal semen
- Increased liver protein levels
- Decreased blood calcium levels

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to the Holder of certificate of registration through the mail: pvg.cdma@heterogroups.com. By reporting side effects, you can help provide more information on the safety of RAVOQUIX.

5. How to store RAVOQUIX

Store at or below 25°C

Protect from moisture

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated on the label

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 RAVOQUIX contains

The active substance is Varenicline Tartrate

Microcrystalline cellulose

Anhydrous dibasic calcium phosphate,

Croscarmellose Sodium

Ferric oxide

Colloidal Silicon Dioxide

Magnesium stearate

Opadry pink

Opadry yellow

What RAVOQUIX looks like and contents of the pack

HDPE bottle:

White opaque high-density polyethylene (HDPE) bottle, closed with a child resistant plastic cap with pulp liner, containing desiccant 2,0 gramme silica gel canister.

Pack sizes: 56 tablets.

Blister strips:

Clear transparent, thermoformable, and rigid PVC film laminated with ACLAR Plain Peel-Push Through foil /Hard tampered plain aluminium foil with HSL coating on bright side

Pack size: 14 tablets per blister, 15 blisters packed in a box

Not all pack sizes may be marketed

The holder of the certificate of registration

Hetero Drugs South Africa (Pty) Ltd**.**

Waterfall corporate campus,

Building no. 2, first floor,

74 Waterfall Drive,

Midrand 2066.

Tel.: 0126441220.

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RAVOQUIX 0,5 mg: 57/34/0873

RAVOQUIX 1 mg: 57/34/0874

Access to the corresponding Professional Information

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