

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S5****VARIMAPIX 0,5 mg film-coated tablets****VARIMAPIX 1 mg film-coated tablets****Varenicline tartrate****Sugar free****Read all of this leaflet carefully before you start taking VARIMAPIX**

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

1. What VARIMAPIX is and what it is used for

VARIMAPIX contains the active substance varenicline. VARIMAPIX is a medicine

used to help you stop smoking, in addition to a behavioural modification programme. VARIMAPIX can help to relieve the craving and withdrawal symptoms associated with stopping smoking. It is recommended that you do not smoke while taking VARIMAPIX.

2. What you need to know before you take VARIMAPIX

Do not take VARIMAPIX:

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

Warnings and precautions

Tell your doctor or health care provider before taking VARIMAPIX

Take special care with VARIMAPIX:

There have been reports of depression, suicidal ideation and behaviour and suicide attempts in patients taking VARIMAPIX. If you are taking VARIMAPIX 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 VARIMAPIX 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 VARIMAPIX, 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 (a medicine 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 VARIMAPIX. 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 VARIMAPIX treatment. Some people have reported seizures while taking VARIMAPIX.

Hypersensitivity reactions

Stop taking VARIMAPIX 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 VARIMAPIX. If you develop a rash or if your skin starts to peel or blister you should stop taking VARIMAPIX and seek emergency medical help.

Children and adolescents

VARIMAPIX is not recommended for use in children below 18 years as efficacy was not demonstrated.

Other medicines and VARIMAPIX

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

If you have severe kidney disease you should avoid taking cimetidine (a medicine used for gastric problems) at the same time as VARIMAPIX as this may cause increased blood levels of VARIMAPIX.

Use of VARIMAPIX with other therapies for smoking cessation

Consult your doctor before using VARIMAPIX in combination with other smoking cessation therapies.

VARIMAPIX with food, drink and alcohol

There have been some reports of increased intoxicating effects of alcohol in patients taking VARIMAPIX. However, it is not known if VARIMAPIX actually increases alcohol intoxication.

Pregnancy, breastfeeding and fertility

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 this medicine.

You should not take VARIMAPIX while you are pregnant.

Women taking VARIMAPIX should not breastfeed their infants.

Driving and using machines

VARIMAPIX may cause 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.

It is not always possible to predict to what extent VARIMAPIX may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which VARIMAPIX affects them.

3. How to take VARIMAPIX

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

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

You are only likely to stop smoking if you are motivated to stop and are provided with additional advice and support from a behavioural modification programme. Your doctor and pharmacist can provide advice, support and sources of further information to help ensure your attempt to stop smoking is successful.

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

You should be treated with VARIMAPIX for 12 weeks.

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

Days 1 - 3:	0,5 mg once daily in the evening
Days 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 VARIMAPIX for a further 12 weeks resulting in a total of 24 weeks of treatment.

If you have the impression that the effect of VARIMAPIX 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 VARIMAPIX.

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

If you take more VARIMAPIX 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 VARIMAPIX

It is important that you take VARIMAPIX 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. Do not take a double dose to make up for forgotten individual doses.

If you stop taking VARIMAPIX

It has been shown in clinical trials that 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 VARIMAPIX, according to the instructions described in the table above, until you have completed your course of VARIMAPIX.

4. Possible side effects

VARIMAPIX can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, tongue and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

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

- seizure, stroke, heart attack,
- suicidal thoughts, loss of contact with reality and unable to think or judge clearly (psychosis), changes in thinking or behaviour (such as aggression and abnormal behaviour),
- severe skin reactions including Erythema Multiforme (a type of rash) and Stevens-Johnson Syndrome (a serious illness with blistering of the skin, mouth, around the eyes or genitals)

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

Tell your doctor if you notice any of the following:

Frequent

- inflammation of the nose and throat,
- abnormal dreams, difficulty sleeping, headache,
- nausea, heartburn, vomiting, constipation, diarrhoea, feeling bloated, abdominal pain, toothache, indigestion, flatulence, dry mouth,
- chest infection, inflammation of the sinuses,
- increased weight, decreased appetite, increased appetite,
- sleepiness, dizziness, changes in the way things taste,
- shortness of breath, cough,
- skin rash, itching,
- joint ache, muscle ache, back pain,
- chest pain, tiredness.

Less frequent

- fungal infection, viral infection,
- feeling of panic, difficulty thinking, restlessness, mood swings, depression, anxiety, hallucinations, changes in sex drive,
- tremor, feeling sluggish, less sensitive to touch,
- conjunctivitis, eye pain,
- ringing in the ears,
- angina, rapid heart rate, palpitations, increased heart rate,
- increased blood pressure, hot flush,
- inflammation of nose, sinuses and throat, congestion of nose, throat and chest, hoarseness, hay fever, throat irritation, congested sinuses, excess mucous from nose causing cough, runny nose,
- red blood in stools, irritated stomach, change of bowel habit, belching, mouth

ulcers, pain in the gums,

- reddening of the skin, acne, increased sweating, night sweats,
- muscle spasms, chest wall pain,
- abnormally frequent urination, urination at night,
- increased menstrual flow,
- chest discomfort, flu like illness, fever, feeling weak or unwell,
- high blood sugar,
- excessive thirst,
- feeling unwell or unhappy, slow thinking,
- increased muscle tension, difficulty with speech, difficulty with coordination, reduced sense of taste, altered sleep pattern,
- disturbed vision, eyeball discolouration, dilated pupils, sensitivity to light, shortsightedness, watery eyes,
- irregular heartbeat or heart rhythm disturbances,
- throat pain, snoring,
- blood in vomit, abnormal stools, coated tongue,
- stiff joints, rib pain,
- glucose in urine, increased urine volume and frequency,
- vaginal discharge, changes in sexual ability,
- feeling cold, cyst,
- diabetes,
- sleep walking.

Frequency unknown

- 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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of VARIMAPIX.

5. How to store VARIMAPIX

Store all medicines out of reach of children.

- Store at or below 30 °C.
- Keep the blisters in the carton until required for use.
- Do not use after the expiry date stated on the label and 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 VARIMAPIX contains

- The active substance is varenicline.

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

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

Sugar free.

- The other ingredients are:

Tablet core (0,5 mg and 1 mg tablets): anhydrous dibasic calcium phosphate,

colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose.

Film coating (0,5 mg tablet): hypromellose 2910, polyethylene glycol 400, titanium dioxide (E171).

Film coating (1 mg tablet): FD&C Blue No. 2--aluminium lake, hypromellose 2910, polyethylene glycol 400, titanium dioxide (E171).

What VARIMAPIX looks like and contents of the pack

VARIMAPIX 0,5: White to off white film-coated tablet.

VARIMAPIX 1: Light blue film-coated tablet.

Starter (initial dosing) pack containing 2 PVC hard film blisters one blister of 11 x VARIMAPIX 0,5 mg film-coated tablets and one blister of 14 x VARIMAPIX 1 mg film-coated tablets. Blisters are packed in a secondary card packaging, and heat-sealed with aluminium foil bags, then packed in a carton with leaflet.

Starter (initial dosing) pack containing 4 PVC hard film blisters: one blister of 11 x VARIMAPIX 0,5 mg film-coated tablets and three blisters of 14 x VARIMAPIX 1 mg film-coated tablets. Blisters are packed in a secondary card packaging, and heat-sealed with aluminium foil bags, then packed in a carton with leaflet.

Follow-on (maintenance) pack containing 2 or 4 PVC hard film blisters of 14 x VARIMAPIX 1 mg film-coated tablets. Blisters are packed in a secondary card packaging, and heat-sealed with aluminium foil bags, then packed in a carton with leaflet.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Website Address: www.trinitypharma.co.za