

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

MAVIK 0,5 mg and 2 mg hard capsules

Trandolapril

Contains sugar:

Each MAVIK 0,5 mg capsule contains 56,0 mg lactose monohydrate

Each MAVIK 2 mg capsule contains 55,5 mg lactose monohydrate

Read all of this leaflet carefully before you start taking MAVIK.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor, pharmacist, nurse or other health care provider.
- MAVIK 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 MAVIK is and what it is used for
2. What you need to know before you take MAVIK
3. How to take MAVIK
4. Possible side effects
5. How to store MAVIK
6. Contents of the pack and other information

1. What MAVIK is and what it is used for

Trandolapril, the active ingredient in MAVIK belongs to a group of medicines called angiotensin-converting enzyme inhibitors (also called ACE inhibitors). ACE inhibitors work by relaxing the blood vessels which makes it easier for the heart to pump blood around the body. This helps to lower the blood pressure.

Trandolapril is used to treat high blood pressure. It may also be used to help protect the heart after a heart attack.

2. What you need to know before you take MAVIK

Do not take MAVIK:

- if you are hypersensitive (allergic) to trandolapril, other angiotensin-converting enzyme (ACE) inhibitors (e.g. perindopril or ramipril) or any of the other ingredients of MAVIK (listed in section 6)
- if you have had the condition known as angioedema (swelling of the hands, face, lips, tongue or throat with difficulty swallowing or breathing, possibly together with an itchy rash such as nettle rash or hives)
- if you or a member of your family, have a history of suffering from angioedema
- if you have aortic stenosis (a type of heart valve disease)
- if you have a thickened heart muscle (hypertrophic obstructive cardiomyopathy (HOCM))
- if you have severe kidney function impairment (when your kidneys are not working as well as they should)
- if you have kidney problems and are taking medicines called fluoroquinolones (antibiotics used to treat certain bacterial infections) at the same time (see **Other medicines and MAVIK** and **Take special care with MAVIK**).
- if you have renal artery stenosis (when one or both the arteries leading to the kidneys becomes narrowed, preventing adequate blood flow to the kidneys)

- if you are pregnant or breastfeeding your baby (see **Pregnancy and breastfeeding**)
- if you are using potassium sparing diuretics called spironolactone, triamterene or amiloride (used to treat high blood pressure or heart failure)
- if you have a condition called porphyria (a group disorders that cause a build-up of certain chemicals in your body)
- if you are using lithium (medicine used to treat mood disorders)
- if you are using aliskiren (medicine use to treat high blood pressure).

Warnings and precautions

Take special care with MAVIK:

- if your kidneys are not functioning normally. Your doctor may perform blood tests before your treatment begins and during your treatment to monitor your blood potassium levels and your kidney function
- if you have severe high blood pressure
- if you are an elderly person (older than 65 years)
- if you have sudden swelling of the lips, tongue, face, throat or neck, possibly also hands and feet, wheezing or hoarseness (this condition is called angioedema and may occur at any time during treatment)
- if you feel dizzy or faint after your first dose, as a few people react to their first dose or when their dose is increased, by feeling dizzy, weak, faint or sick
- if you have high temperature, sore throat or mouth ulcers (these may be symptoms of infection caused by the lowering of the number of white blood cells)
if you experience yellowing of the skin and whites of eyes (jaundice) or blood tests show an increase in liver enzymes, these may be signs of liver disease or your liver not functioning normally
- if you have recently started or been taking diuretics ("water tablets") for a long time, or are on a low salt diet

- if you have heart problems (ischaemic heart disease)
- if you have cerebrovascular disease (stroke)
- if you have or have had severe or prolonged vomiting or diarrhoea
- if you have been told that you have a narrowing of the blood vessels to one or both of your kidneys (renal stenosis)
- if you suffer from a condition known as collagen vascular disease (this is sometimes called connective tissue disease, for example lupus or scleroderma). You are more likely to experience changes to your blood that can cause you to develop an infection
- if you are dark-skinned, as MAVIK may be less effective at lowering your blood pressure or MAVIK may increase the risk of angioedema
- if you suffer from diabetes mellitus, as MAVIK could cause your blood glucose levels to decrease too much
- if you suffer from stomach pain, possibly also feeling sick or being sick. This may be a symptom of angioedema in the stomach (intestinal angioedema)
- if you experience pain when swallowing, severe sore throat and difficulty breathing, you may have oedema extending to the glottis, which is life-threatening. Consult your doctor immediately, should this occur. Your doctor will administer the correct medicine to you
- if you are on kidney dialysis as you may be at risk of serious allergic reactions (some kinds of dialysis membrane may not be suitable). You may need to be monitored more closely by your doctor
- if you are taking any of the following medicines, the risk of angioedema (rapid swelling under the skin in area such as the throat) is increased (see **Other medicines and MAVIK**):
 - sirolimus, everolimus or temsirolimus and other medicines belonging to the class of mTOR inhibitors (used to avoid rejection of transplanted organs)
 - vildagliptin, a medicine used to treat diabetes
- if you have other liver or kidney problems including if you have had a kidney transplant

- if you need to have major surgery or will be given an anaesthetic, tell your doctor, dentist or health care provider that you are taking MAVIK, because taking MAVIK at this time could cause your blood pressure to drop further
- if you have a persistent cough
- if you are to undergo LDL apheresis (which is removal of cholesterol from your blood by a machine)
- if you are going to have desensitisation treatment to reduce the effects of an allergy to stings (such as bee or wasp)
- if you have diabetes-related kidney problems.

Other medicines and MAVIK

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

The following medicine may cause an interaction when taking in combination with MAVIK:

- antihypertensives (used to treat high blood pressure)
- nonsteroidal anti-inflammatory drugs (NSAIDs) (used to treat pain, inflammation and swelling)
- potassium-sparing diuretics (e.g. spironolactone, triamterene or amiloride), potassium supplements or potassium-containing salt substitutes (used to treat high blood pressure and heart failure)
- trimethoprim and cotrimoxazole (used to treat certain bacterial infections)
- ciclosporin (used to prevent organ transplant rejection)
- heparin (used to thin blood to prevent clots)
- antacids (used to treat heartburn)
- lithium (used to treat mood disorders)
- insulin or oral hypoglycaemic medicines (used to treat diabetes)
- neuroleptics (used to treat and manage symptoms of many psychiatric disorders)

- tricyclic antidepressants (used to treat depression)
- racecadotril (used to treat symptoms of acute (short term) diarrhoea)
- sirolimus (used in combination with other medicines to prevent rejection of kidney transplants)
- everolimus (used to treat advanced (late-stage) cancers or noncancerous tumours)
- temsirolimus (used to treat advanced renal cell carcinoma (a type of cancer that begins in the kidney))
- vildagliptin (used to treat type 2 diabetes)
- hypnotics (used to treat insomnia, which is characterised by difficulties with falling asleep or maintaining sleep)
- narcotics (used to treat severe pain)
- anaesthesia (used to prevent pain during surgery and other procedures)
- sympathomimetic medicines (used to treat heart disorders, low blood pressure or glaucoma)
- allopurinol (used to treat gout and kidney stones)
- procainamide (used to treat heart arrhythmias)
- cimetidine (used to treat and prevent ulcers of the stomach and intestines)
- medicines containing sodium aurothiomalate (gold) (used in the treatment of rheumatoid arthritis)
- aliskiren (used to treat high blood pressure)
- fluoroquinolones (antibiotics used to treat certain bacterial infections).

MAVIK with food, drink and alcohol

MAVIK capsules may be taken with/without meals, preferably at the same time every day.

Drinking alcohol increases the blood pressure lowering effect of MAVIK.

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 health care provider for advice before taking MAVIK.

Driving and using machines

MAVIK may cause dizziness, drowsiness, unusual tiredness or blurred vision, which may affect your ability to drive a vehicle and use machines. Take special care when performing tasks requiring your attention, until you know how you will react to MAVIK.

MAVIK contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking MAVIK.

MAVIK contains sodium

MAVIK contains less than 1 mmol (23 mg) sodium per hard capsule, that is to say essentially "sodium-free."

3. How to take MAVIK

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

Swallow your capsules whole without chewing them and take them with a glass of water.

Always take your MAVIK capsules at the same time of day.

The number of capsules that you will need to take will depend on what you are treated for.

If you are already taking diuretics ("water pills") your doctor may tell you to reduce the dose of the diuretic or even tell you to stop taking it before you start to take MAVIK.

The recommended starting dose is 0,5 mg once a day. Your doctor will probably increase this dose to 1 – 2 mg daily. The maximum dose is 4 mg a day.

Special populations:

Elderly patients

It is not necessary to reduce the dose if you have normal kidney function. Your doctor will watch your blood pressure and measure your kidney function during treatment.

However, caution is needed if at the same time you are being treated with diuretics (water tablets) or you have reduced heart, liver or kidney function.

Patients with kidney problems

Your doctor will adjust your dose depending on the results of your laboratory tests (0,5 – 1 mg daily). If you are undergoing kidney dialysis, the MAVIK dose is started at 0,5 mg daily.

Patients with liver problems:

The initial dose is 0,5 mg daily. Afterwards your doctor may adjust your dose as needed.

Children and adolescents

MAVIK should not be given to children.

If you take more MAVIK 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 MAVIK

If you forget to take your MAVIK capsules, take it as soon as possible. Do not take a double dose to make up for a forgotten dose.

If you stop taking MAVIK

It is important that you keep taking the capsules until your doctor tells you to stop. Do not stop

just because you feel better. If you stop taking the capsules, your condition may get worse.

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

4. Possible side effects

MAVIK can have side effects.

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

If any of the following happens, stop taking MAVIK 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
- rash or itching
- fainting.

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

- weakness, unexplained or abnormal bruising or bleeding or more frequent, potentially severe, infections (this may be signs of a severe reduction of all types of blood cells)
- irregular heartbeats (palpitations or arrhythmia), fast or slow
- myocardial infarction (heart attack)
- myocardial ischaemia (angina pectoris) is chest pain, similar to indigestion or heartburn
- heart failure (cardiac insufficiency)
- a rapid heartbeat that may be regular or irregular (tachycardia)

- a slow or irregular heartbeat (bradycardia)
- difficulty in breathing (dyspnoea)
- yellowing of the skin and eyes, dark urine and tiredness (symptoms of liver problems, also called jaundice or cholestasis).
- heart disorder such as AV block (characterised by dizziness, fainting, tiredness and shortness of breath)
- sudden, unexpected loss of heart function, breathing and consciousness (cardiac arrest)
- tightness in chest (bronchospasm)
- less urine than is normal for you (your kidneys not functioning normally)
- stroke (cerebrovascular event), brain bleeding.

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:

- headache, dizziness, spinning sensation (vertigo)
- low blood pressure (dizziness or light headedness)
- coughing
- abnormal physical weakness or lack of energy (asthenia)

Less frequent side effects:

- infection, inflammation or congestion of the upper respiratory tract (coughing, runny nose or sore throat)
- bronchitis (persistent cough)
- pharyngitis (difficulty swallowing, hoarse voice, swollen lymph nodes)
- high sugar levels in blood
- low levels of sodium in your blood
- high levels of cholesterol or fat particles in your blood

- an abnormally high level of uric acid in the blood, associated with gout
- loss of appetite for food (anorexia) or increased appetite
- sleep disorder (insomnia)
- decreased sexual drive (libido)
- seeing or hearing things that do not exist (hallucinations)
- feeling depressed, anxious, agitated or have a lack of interest
- drowsiness (sleepiness)
- syncope (fainting)
- myoclonus (sudden, brief involuntary twitching or jerking of a muscle)
- paraesthesia ("pins and needles")
- migraine (very severe headache)
- changes in taste
- swollen eye lids, swelling of the tissue that lines the eyelids and surface of the eye (conjunctiva), visual disturbances, eye disorders
- ringing or buzzing in the ears
- hot flushes, high blood pressure
- angiopathy (a disease of the blood vessels)
- blood circulation disorder
- twisted, enlarged veins, most commonly appearing in the legs and feet (venous varicosis)
- nose bleeds
- nausea (feeling sick), vomiting (being sick), diarrhoea, constipation, gastrointestinal disorders, vomiting of blood, heartburn, dry mouth, flatulence (wind)
- excessive sweating, silver scaly plaques on your skin (psoriasis) or inflamed, swollen, red, itchy, weeping or crusty skin (eczema), acne or dry skin
- back ache, muscle spasms, pain in the arms or legs
- pain in the joints or bones, stiffness
- azotaemia (elevated levels of urea and other nitrogen compounds in the blood)

- passing abnormally large amounts of urine (polyuria)
- abnormally frequent urination (pollakiuria)
- difficulty maintaining an erection
- skin disorder characterised by dry, scaly or thickened skin (ichthyosis)
- unusual weakness or tiredness, lack of energy
- high levels of bilirubin in the blood (these may be signs of problems with your liver or a blockage in your bile duct)
- injury

Frequency unknown:

- sinusitis (runny nose or blocked or stuffy nose)
- rhinitis (sneezing, stuffy or itchy nose)
- glossitis (swollen, painful or glossy tongue)
- high levels of potassium in the blood
- mental confusion, mood disorders
- balance disorder
- blurred vision
- obstruction of the bowel, inflammation of the pancreas (pain in the upper stomach area), swelling of the lining of the intestines (intestinal oedema), indigestion
- inflammation of the skin (dermatitis)
- hair loss (temporary), hives
- severe skin condition with blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens-Johnson syndrome)
- severe skin reactions starting with painful red areas, large blisters and ends with peeling of layers of skin, accompanied by fever and chills, aching muscles and generally feeling unwell (toxic epidermal necrolysis)
- rash or sunburn, especially on areas of the skin that are exposed to sun light

- muscle pain
- increase of creatinine, urea, alkaline phosphatase, lactate dehydrogenase in your blood
- abnormally high levels of waste products in the blood (uraemia)
- abnormally small production of urine (oliguria) or lack of urine production (anuria)
- fever.

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 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 MAVIK.

5. How to store MAVIK

Store in a dry place, at or below 25 °C.

Store the capsules in the outer carton until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use after the expiry date printed on the carton.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What MAVIK contains

The active substance is trandolapril.

Other ingredients are: maize starch, lactose monohydrate, povidone (Type K25), sodium stearyl fumarate.

The capsule shell contains gelatine, titanium dioxide (E171), sodium laurilsulfate.

Colourants include iron oxide yellow (E172), erythrosine (E127).

What MAVIK looks like and contents of the pack

MAVIK 0,5 mg: No. 4 capsule consisting of a red body and a yellow cap, containing practically white granules.

MAVIK 2 mg: No. 4 capsule consisting of a red body and a red cap, containing practically white granules.

Pack of 30 capsules. Capsules are enclosed in PVC blister strips, with aluminium foil backing.

Holder of Certificate of Registration

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This leaflet was last revised in

MAVIK 0,5 mg: 27 November 2023

MAVIK 2 mg: 27 November 2023

Registration numbers

MAVIK 0,5 mg: 28/7.1.3/0261

MAVIK 2 mg: 28/7.1.3/0263