PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

TARKA 180/2 prolonged-release tablets

TARKA 240/4 prolonged-release tablets

TARKA 180/2

Contains sugar: 107 mg lactose monohydrate per tablet.

TARKA 240/4

Contains sugar: 110,37 mg lactose monohydrate per tablet.

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

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

1. What TARKA is and what it is used for

TARKA belongs to the group of blood pressure lowering medicines (also known as antihypertensives). It contains two different types of active substances:

- A calcium channel blocker (verapamil); and
- An angiotensin-converting enzyme (ACE) inhibitor (trandolapril)

TARKA tablets are used to treat hypertension (high blood pressure) in patients where trandolapril or verapamil alone are found to be ineffective.

2. What you need to know before you take TARKA

Do not take TARKA if:

- You are hypersensitive (allergic) to verapamil hydrochloride, trandolapril, another angiotensin-converting enzyme (ACE) inhibitor, or to any of the excipients of TARKA (see section 6).
- You are pregnant or planning to become pregnant.
- You are breastfeeding.
- You have a family history, or you have had a severe allergic reaction, such as swelling of your face, tongue or throat (known as angioedema), to any of the group of medicines known as ACE inhibitors or angiotensin-receptor blocker.
- Your blood pressure is extremely low (e.g. during shock) due to severe heart disease.
- You have recently had a serious heart attack with complications.
- You do not wear a pacemaker, and you have been told by your doctor that you have second- or third-degree heart block or sick sinus syndrome.
- You have been told by your doctor you have heart problems, such as heart failure, sinoatrial block, left ventricular dysfunction, aortic or mitral valve stenosis or outflow syndrome obstruction, a condition called Wolff-Parkinson-White (WPW) or the Lown-Ganong-Levine syndrome.
- You have an abnormally slow or irregular heartbeat.
- You are taking medicine containing ivabradine for the treatment of heart failure.
- You have severe liver dysfunction, or liver cirrhosis associated with fluid accumulation (swelling) of the abdomen.
- You suffer from moderate to severe kidney impairment, or you require dialysis treatment.

- You have a condition known as bilateral renal artery stenosis or renal artery stenosis if you only have one kidney. Bilateral artery stenosis is a condition where the major blood vessels supplying both kidneys are blocked or narrowed. Renal artery stenosis is where the blockage or narrowing occurs, in the case of a person who only has one kidney.
- You have an overactive adrenal cortex with increased production of the hormone aldosterone (primary aldosteronism).
- You are on treatment with water pills such as spironolactone, triamterene and amiloride.
- You suffer from porphyria.
- You suffer from Addison's disease and are on treatment with water pills known as thiazide diuretics.
- You are on treatment with lithium (used to treat depression or mood disorders).
- You are being treated with intravenous beta blockers (except for intensive care unit patients);
- You have diabetes mellitus (high blood sugar) or you have impaired kidney function and you are taking antihypertensive medicine containing aliskiren.
- You are taking sacubitril/valsartan (medicine to treat chronic heart failure in adults). You must only start taking your dose of TARKA at least 36 hours after the last dose of sacubitril/valsartan. Ask your doctor if you are unsure.

TARKA is not suitable for children and adolescents under the age of 18 years.

If you are unsure if any of the list applies to you, ask your doctor before you start to take your TARKA tablets.

If you suffer from any of the above, please tell your doctor or pharmacist.

Warnings and precautions:

There are some medical conditions that may mean your doctor will need to monitor you more closely. Please talk to your doctor or pharmacist before taking TARKA:

- If you are dehydrated, you are taking water tablets (diuretic medicines), you are following a salt-restricted diet, you are experiencing diarrhoea or you are vomiting.
- If you have liver or kidney problems or recently underwent a kidney transplant.

- If you are suffering from collagen disease, including an immune system disorder such as systemic lupus erythematosus (a condition causing joint pain, rash and fever) or scleroderma (a condition leading to hardening and thickening of the skin and possibly to hair loss. You are at risk of developing abnormal white blood cell counts while taking TARKA. Contact your doctor if you experience any tiredness, unexplained fever, or increased infections.
- If you have diabetes (high blood sugar).
- If you are elderly.
- If you are to undergo a surgical procedure, or you require anaesthesia.
- If you suffer from a heart condition known as first degree atrioventricular block (a nerve blockade in your heart causing a slow heartbeat) or hypertrophic obstructive cardiomyopathy (thickening of your heart muscle).
- If you have bradycardia (your heart beats slower than normal).
- You are suffering from neuromuscular dysfunction such as myasthenia gravis (chronic fatigue and muscle weakness), Lambert-Eaton syndrome or advanced muscular dystrophy such as Duchenne's muscular dystrophy.
- If you are undergoing desensitization treatment to prevent allergic reactions.
- If you are undergoing LDL apheresis (mechanical removal of cholesterol from the blood).

Some patients have had severe allergic reactions after taking TARKA. These reactions include an itchy rash and/or swelling of your eyes, face, lips, tongue or throat, difficulty breathing (angioedema); or severe allergic intestinal reactions causing abdominal pain (with and without nausea and vomiting) (intestinal oedema).
If you experience any of these symptoms, stop taking TARKA, and tell your doctor immediately.

Tell your doctor as soon as possible if you notice any of the following:

- Your skin or eyes turn yellow or your belly becomes sore.
- You feel dizzy and faint and your blood pressure is low.
- An allergic reaction where your skin breaks out with hives (red raised bumps) or sores.

- Your blood pressure may drop lower than normal when you first start TARKA or if your doctor increases your dose, this can make you feel dizzy or tired.

Children and adolescents:

TARKA is not suitable for children and adolescents under the age of 18 years.

Other medicines and TARKA:

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

In particular tell your doctor if you are using any of the following medicines:

- Racecadotril (used to treat diarrhoea).
- Sirolimus, everolimus, temsirolimus, tacrolimus, ciclosporin (used to prevent rejection after an organ transplant).
- Antidiabetic medicines, vildagliptin, metformin, glibenclamide (used to treat high blood sugar).
- Potassium-sparing diuretics (such as spironolactone, triamterene or amiloride (used to treat high blood pressure or heart failure).
- Potassium supplements.
- Trimethoprim (antibiotic used to treat bladder infections).
- Cotrimoxazole (used to treat bacterial infections).
- Heparin, dabigatran, rivaroxaban, other anticoagulant medicines (used to prevent blood clots).
- Other antihypertensive medicines, including ACE inhibitors, angiotensin II receptor antagonists, prazosin, terazosin (used to treat high blood pressure).
- Dantrolene, muscle relaxants (used to treat muscle stiffness or spasms).
- Ivabradine (used to treat heart failure).
- Protease inhibitors, including ritonavir (used to treat HIV or AIDS).
- Colchicine (used to treat inflammation or gout).
- Gold/sodium aurothiomalate injections (used to treat adult or juvenile rheumatoid arthritis).
- Diuretic medicine (used to treat high blood pressure and reduce water retention).
- Anaesthetics (used to create a loss of awareness during surgery).

- Narcotics (used to relief pain).
- Antipsychotic medicines (used to treat psychosis).
- Sedatives (used to make you feel more relaxed).
- Antidepressant medicines, imipramine (used to treat depression).
- Allopurinol (used to treat gout).
- Cytostatic medicines, doxorubicin (used to treat cancer).
- Systemic corticosteroids, steroids (such as prednisone or cortisone) (used to treat inflammation).
- Procainamide, quinidine (used to treat an abnormal heartbeat).
- Digitalis medicines such as digoxin or digitoxin (used to treat heart failure or an irregular heartbeat).
- NSAIDs or aspirin (used to treat pain).
- Antacids (used to treat indigestion, heartburn or stomach ulcers).
- Antidiabetic medicines, glibenclamide, metformin (used to treat high blood sugar)
- Carbamazepine, phenobarbital, phenytoin (used to control seizures).
- Lithium (used to control depression or anxiety).
- Buspirone (used to treat anxiety).
- Metoprolol (used to treat hogh blood pressure and angina).
- Midazolam (used as a sedative during anaesthesia).
- Propranolol (used to treat heart problems and migraines).
- Theophylline (used to control asthma).
- Triptan class medicines, including almotriptan (used to control migraine headaches).
- Simvastatin, atorvastatin (certain medicines to lower your cholesterol levels).
- Antibiotic medicines such as clarithromycin, erythromycin, telithromycin (used to treat bacterial infections) or rifampicin (used to treat tuberculosis (TB)).
- Sulfinpyrazone (helps the kidneys to lower high levels of uric acid in your body).
- Cimetidine (used to treat stomach ulcers).
- The herbal medicine, St. John’s wort (used to treat mental health problems).

Remember to tell your doctor that you are taking TARKA if you need to have any blood tests. It may affect the test results.

TARKA with food and drink:

Avoid grapefruit juice while using TARKA. This may increase your risk of side effects from TARKA. (See HOW TO TAKE TARKA).

Avoid alcohol while using TARKA. TARKA will increase the time it takes your body to get rid of alcohol.

Pregnancy and breastfeeding:

Do not take TARKA if you are pregnant, planning to become pregnant or if you are breastfeeding. The medicine in TARKA may affect your baby. Tell your doctor immediately if you become pregnant.

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 TARKA.

Do not breastfeed if you are taking TARKA. You should be aware that the medicine in TARKA might pass into your breast milk.

Driving and using machines:

Until you are aware of how TARKA affects you, you should not drive a vehicle, operate dangerous tools or large machinery, or do anything that requires you to be alert.

Avoid alcohol while using TARKA. TARKA will increase the time it takes your body to get rid of alcohol.

TARKA contains lactose and sodium

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

TARKA 180/2 contains 25,7 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 1,29 % of the recommended maximum daily dietary intake of sodium for an adult.

TARKA 240/4 contains 34,3 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 1,72 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take TARKA

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

Always take TARKA exactly as your doctor has told you. If you are not sure, you should check with your doctor or pharmacist.

- The number of tablets that you will need to take will be decided by your doctor.
- However, the usual dose is one tablet taken once a day, preferably in the morning, before with or after breakfast.

  Swallow your tablets without chewing them. If it helps, you can wash them down with a glass of water. It does not matter if you have not eaten.
- You should avoid taking your tablets at the same time as antacid medicines or grapefruit juice, which can affect the absorption of the medicine. This does not occur with other fruit juices such as orange, apple or tomato juice.
- This product is not suitable for use in children.

It is important that you keep taking these tablets until your doctor tells you to stop. Don’t stop just because you feel better. If you stop taking the tablets too soon, your condition may get worse.

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

If you take more TARKA 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 do take too much TARKA, you may feel sleepy or dizzy due to a large drop in blood pressure and slowing of your heartbeat. Seek emergency medical assistance if this occurs, because you may need medical treatment.

If you forget to take TARKA:

If you forget to take one of your doses, take another as soon as you remember, but only if you remember on the same day as the missed dose. If not, do not take the missed dose at all. Never take two doses to make up for the one you missed.

4. Possible side effects

TARKA can have side effects.

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

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

- swelling of your 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 TARKA. 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:

- if you experience any heart problems, including changes in the way your heart beats, such as beating slower or faster than normal or skipping beats (palpitations), chest pain, heart failure or a heart attack (chest pain, shortness of breath, pain or discomfort in your arm), and changes on an electrocardiogram when tests are done,
- increased frequency of infection and unexplained fever,
- unexplained bruising or bleeding, causing pintpoint bleeds on your skin or nosebleeds,
- loss of consiousness,
- bleeding on your brain (sudden numbness of your face, arm or leg, severe headache, nausea, vomiting, confusion, dizziness, seizures),
- stroke or transient ischemic attack (numbness and weakness on one side of your body, difficulty moving or speaking, confusion),
- asthma or shortness of breath,
- yellowing of your skin or eyes, dark urine, and tiredness, which may be symptoms of liver problems, including jaundice, hepatitis or cholestasis,
- severe, painful, blistering skin rash known as erythema multiforme, Steven-Johnson syndrome, or toxic epidermal necrolysis,
- kidney problems or changes in your kidney function,
- heamolytic aneamia (tiredness, weakness, pale skin, shortness of breath, dark urine),
- brief and repeated jerks of the eyelids and eyeballs that roll upwards (myoclonia),
- paralysis (loss of movement in your body),
- vomiting blood,
- severe allergic reactions that may affect your intestines and cause abdominal pain (with and without nausea and vomiting) (intestinal angioedema).

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

Tell your doctor if you notice any of the following:

Side effects which occur frequently:

- headache, dizziness,
- vertigo,

- low blood pressure,
- sudden drop in your blood pressure when you sit or stand up too quickly (light-headedness or dizziness),
- flushing,
- hot flushes,
- cough,
- constipation.

Side effects which occur less frequently:

- Herpex simplex infections (viral infection causing small fluid filled blisters/sores on your genitals or your mouth (fever blisters) causing itching, sensitivity or pain in the area),
- bronchitis (inflammation of your airways causing coughing, mucus, shortness of breath, chest discomfort),
- high cholesterol (high levels of fat in your blood),
- anorexia (severe weight loss),
- feeling depressed, nervous or anxious,
- increased aggression,
- insomnia (inability to sleep),
- tremor (uncontrolled shaking),
- drowsiness,
- problem keeping your balance,
- excessive physical sensitivity of your skin,
- pareasthesia (numbness or tingling sensation of yout skin (pins and needles)),
- taste disorder,
- vision problems, including blurred vision,
- fluctuations in your blood pressure,
- sinus congestion (blocked nose),
- nausea (feeling sick), diarrhoea, pain in your stomach area, stomach problems, vomiting (being sick), dry throat, dry mouth,

- pancreatitis (inflammation of your pancreas causing nausea, vomting, pain in the stomach are radiating to your back),
- abnormal liver values or blood results when tests are done,
- increased sweating,
- hair loss,
- skin disorders, including dermatitis (red, dry, itchy or inflammed skin), psoriasis (skin disease causing a rash, itchy scaly patches on your knees, elbows, body or scalp),
- hives (red, raised bumps on your skin),
- joint pain, muscle pain, muscle weakness,
- excessive urination,
- impotence (inability to get or maintain an erection),
- increased breast tissue (in men),
- swelling of your hands, feet, arms or leg due to excessive fluid retention,
- weakness or tiredness (fatigue).

Side effects which may occur, but the frequency is not known:

- infection or inflammation of your upper airways, including sore throat, sinus inflammation or runny nose,
- redness or inflammation of your tongue (glossitis),
- urinary tract infection (painful and frequent urination),
- increased appetite,
- increased levels of potassium in your blood (pain in your stomach area, diarrhoea, changes in the way your heart beats),
- increased sugar and cholesterol (fat) levels your blood,
- too low level of sodium in your blood (tiredness, weakness, confusion, seizures),
- increased levels of uric acid in your body and gout (painful, red, swollen joints),
- changes in the enzye levels in your body when tests are done,
- sleep disorders,
- hallucinations (seeing or hearing things that are not real),

- lack of libido (sexual drive),
- feeling confused,
- migraine (severe headache),
- uncontrolled shaking, muscle spasms and involuntary movement of your muscles,
- inflammation of your eyelids, swelling of the membrane that covers your eye, eye problems,
- tinnitus (ringing in your ears),
- high blood presssure,
- damage or narrowing of your blood vessels (angiopathy), varicose veins,
- bronchospasms (excessive coughing, weezing or asthma),
- productive cough (with mucus and phlegm),
- nose bleeds,
- discomfort of your stomach area, indigestion, inflammation of your stomach (diarrhoea, nausea, or vomiting), excessive wind (flatulence), overgrowth of your gums,
- ileus (abnormal movement of your intestines (bowels) causing swollen abdomen, pain and constipation),
- episodes of burning pain and redness in the feet, and sometimes the hands, arms, legs, ears and face,
- purple coloured spots on your skin, eczema (dry, flaky and itchy skin patches), acne (pimples), dry skin,
- backache, pain in your extremities or bones, arthritis (painful and stiff joints), muscle spasms,
- increased need to urinate,
- milky discharge from your breasts,
- fever,
- a general feeling of discomfort or unease.

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 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: http://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of TARKA.

5. How TARKA is stored

Store at or below 25 ˚C.

Protect from light and humidity.

Store all medicines out of reach of children.

Keep your tablets in the carton.

Do not take your tablets after the expiry date shown on the carton and blister.

Return all unused medicines to your pharmacist.

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

6. Contents of the pack and other information

What TARKA contains:

Each **TARKA** 180/2 tablet contains 180 mg verapamil hydrochloride and 2 mg trandolapril.

Each **TARKA** 240/4 tablet contains 240 mg verapamil hydrochloride and 4 mg trandolapril.

Other ingredients include anhydrous silica, black ferric oxide, docusate sodium, hydroxypropylcellulose, hypromellose, lactose monohydrate, macrogol, magnesium stearate, maize starch, microcrystalline cellulose, povidone, red ferric oxide, sodium alginate, sodium, stearyl fumarate, talc, titanium dioxide, and yellow ferric oxide.

Excipients with known effect:

TARKA 180/2

Contains sugar: 107 mg lactose monohydrate per tablet.

Each tablet contains 25,7 mg sodium.

TARKA 240/4

Contains sugar: 110,37 mg lactose monohydrate per tablet.

Each tablet contains 34,3 mg sodium.

What TARKA looks like and contents of the pack:

TARKA 180/2 tablets are pink, oval film-coated tablets, with “182” embossed on one side and plain on the other side.

TARKA 240/4 tablets are red-brown, oval film-coated tablets, with “244” embossed on one side and plain on the other side.

Cartons containing 28 tablets. The tablets are enclosed in colourless, transparent PVC/PVDC blister strips with an aluminium foil backing.

Holder of certificate of registration:

Abbott Laboratories S.A. (Pty) Ltd

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Constantia Kloof

1709

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