

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### TARKA

180 mg/2 mg modified-release tablets

VERAPAMIL HYDROCHLORIDE / TRANDOLAPRIL

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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#### What is in this leaflet?

1. What TARKA is and what it is used for
2. Before you take TARKA
3. How to take TARKA
4. Possible side effects
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#### 1. WHAT TARKA IS AND WHAT IS IT USED FOR

TARKA 180 mg/2 mg tablets are 'modified release' which means that they release medicine slowly over several hours.

TARKA is used to treat high blood pressure in patients whose blood pressure has already been controlled on the combination of verapamil SR 180 mg and trandolapril 2 mg.

TARKA belongs to the group of blood-pressure lowering medicines, (also called anti-hypertensives).

TARKA contains two different types of medicines:

- a calcium channel blocker (verapamil)
- an Angiotensin Converting Enzyme (ACE) inhibitor (trandolapril)

#### 2. BEFORE YOU TAKE TARKA

##### **Do not take TARKA if**

- You are allergic (hypersensitive) to trandolapril or other ACE inhibitors, to verapamil or to any other ingredients of TARKA tablets (Section 6 contains a list of ingredients).
- You (or a member of your family) has ever had a severe allergic reaction to any other ACE inhibitor such as swelling in the face, tongue or throat (angioneurotic oedema).

- Your blood pressure is extremely low as a result of severe heart problems (such as during shock).
  - You have recently had a severe heart attack.
  - You have been told by your Doctor that you have heart failure or second or third degree heart block (impaired nerve signal in the heart – causing a very slow heart beat) or an electrical abnormality of the heart causing periods of very fast heartbeat (Wolff-Parkinson-White Syndrome).
  - You have problems with your heart valves or ‘sick sinus syndrome’ (irregular heartbeat) and you do not wear a pacemaker.
  - You have obstructive hypertrophic cardiomyopathy (swelling of the heart muscles).
  - You have severe liver problems, including a condition with fluid in the abdomen (ascites).
  - You have severe kidney disease or require dialysis.
  - You have a condition where the adrenal gland produces too many hormones (primary aldosteronism).
  - You are more than 3 months pregnant (It is also better to avoid TARKA in early pregnancy – see pregnancy section.)
  - You are under 18 years of age.
  - You are being treated with injectable beta-blockers (except in an intensive care situation).
- If you have any questions or are not sure about any of the above, please talk to your doctor or pharmacist.

### ***Take special care with TARKA***

Your doctor may choose to closely monitor your blood pressure and take blood samples at the start of treatment and after dose changes if:

- You are elderly (older than 65 years of age).
- You have diabetes.
- You have liver or kidney problems, or have recently had a kidney transplant.
- You have ever had or are at risk of a heart attack or stroke.
- You are taking lithium (a medicine used in the treatment of mania).
- You have been on a salt restricted diet, or have been vomiting, had diarrhoea or have had diarrhoea recently, are dehydrated, or are taking diuretic medicines (sometimes called “water pills”) or other medicines which may alter your potassium levels.

### ***Tell your doctor if any of the following apply to you:***

Heart disease:

- You have a slow or irregular heart beat.
- You have been told by your doctor that you have either first degree heart block (nerve block in the heart causing a slow heart beat) or left ventricular dysfunction (the left side of your heart pumps poorly).

Other conditions:

- You are using TARKA and medicines affecting the immune system (e.g. ciclosporin), or have an immune system disease such as systemic lupus erythematosus (a condition which causes joint pain, skin rashes and fever) or scleroderma (a condition leading to hardening and thickening of the skin and possible hair loss) as you may be at increased risk of low levels of white blood cells.
- You have a neuro-muscular disorder such as myasthenia gravis (chronic fatigue and muscular weakness), Lambert-Eaton syndrome or advanced Duchenne muscular dystrophy.
- You are having injections to prevent allergic reactions to bee stings (desensitisation therapy)
- You are unable to tolerate some sugars (such as lactose or galactose).
- You think you are (or might become) pregnant. TARKA is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).
- You are breastfeeding (see section ‘Pregnancy and Breastfeeding’).

Allergic reactions:

- In rare instances some patients have had severe allergic reactions after taking ACE inhibitors such as TARKA. These reactions are more common in black people, and can result in an itchy rash and/or the swelling of the face, lips, tongue and throat (angioneurotic oedema). Severe allergic reactions may also affect the gut and

cause belly pain (with or without nausea and vomiting) (intestinal angioedema). If any of this occurs, stop taking TARKA and seek immediate medical assistance.

### ***Taking other medicines***

Several medicines can cause unwanted reactions if used with TARKA. Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription or any herbal medicines. In particular tell your doctor if you are taking any of the following medicines:

Medicines to prevent heart problems or high blood pressure:

- diuretics (also called “water pills”), salt substitutes or potassium pills.
- any medicines used to control your heartbeat, (such as beta blockers, digoxin, or other medicines used to control irregular heartbeats) or your blood pressure. They may cause your blood pressure to become too low or may slow your heart beat too much.

Medicines to treat psychological problems:

- any medicines to treat depression, or psychosis such as imipramine, lithium, midazolam, buspirone, or tranquilizers.

Medicines to prevent organ transplant rejection: such as ciclosporin, tacrolimus, everolimus.

Medicines to treat pain or reduce swelling such as:

- steroids (for example, cortisone or prednisone).
- certain anti-inflammatory medicines or pain-killers (for example, naproxen, ibuprofen or aspirin, or opioids such as morphine).

Medicines to lower your cholesterol or blood fat levels: such as “statins” eg. simvastatin, atorvastatin.

Medicines to treat diabetes: such as insulin or tablets for diabetes.

Medicines to treat epilepsy or seizures: such as phenytoin, carbamazepine and phenobarbital.

Medicines to treat indigestion or stomach ulcers: such as antacids and cimetidine.

Other medicines that may react with TARKA:

- Medicines to treat asthma, such as theophylline.
- Medicines to treat infections or tuberculosis, such as rifampicin, clarithromycin or erythromycin.
- Medicines to treat cancer, such as doxorubicin.
- Medicines to treat or prevent gout, such as allopurinol and colchicine.
- Medicines used in surgery: tell your surgeon that you are taking TARKA prior to having surgery as TARKA may interfere with anaesthetic gases or muscle relaxant medications or other medicine used during surgical procedures such as dantrolene.

This is not a complete list of medicines which may interfere with TARKA. Ask your doctor or pharmacist for advice before taking any medicine with TARKA.

### ***Taking TARKA with Food and Drink***

It is recommended that TARKA is taken at the same time each day, before, with or after breakfast.

Alcohol

Avoid alcohol while using TARKA. You may experience greater blood pressure lowering effects than usual.

Grapefruit juice

Do not drink grapefruit juice while you are taking TARKA. Grapefruit juice may increase the amount of verapamil which your body absorbs. This may increase your risk of side effects from TARKA.

### ***Pregnancy and Breastfeeding***

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking TARKA before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of TARKA. TARKA is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

### ***Breastfeeding***

Tell your doctor if you are breast-feeding or about to start breast-feeding. TARKA is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely. Ask your doctor or pharmacist for advice before taking any medicine.

### ***Driving and using Machines***

Your ability to drive safely or to use heavy machines may be affected. It may make you feel dizziness or fatigue.

Until you are aware how TARKA affects you, you should not drive a vehicle or operate dangerous tools or large machinery.

### ***Important information about some of the ingredients of TARKA***

Lactose:

TARKA tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## ***3. HOW TO TAKE TARKA***

Always take your TARKA tablets exactly as your doctor has instructed.

You should check with your doctor or pharmacist if you are not sure how to take TARKA. The dose of TARKA has been selected by your doctor as the most appropriate to control your blood pressure.

The usual dosage is one TARKA modified-release tablet taken once every day in the morning before, with or after breakfast. The tablet should be swallowed whole with a glass of water, without sucking, chewing or crushing it.

### ***If you take more TARKA than you should***

If you believe you have taken too much TARKA you should immediately contact your doctor or pharmacist, some situations may require emergency medical treatment.

If you take too much TARKA you may feel sleepy or dizzy, due to a large drop in your blood pressure and slowing of your heartbeat. Other symptoms that may occur if you take too much TARKA are: shock (sudden drop in blood pressure or heart rate), stupor, kidney failure, fast breathing, fast heartbeat, irregular heartbeat, anxiety and cough.

### ***If you forget to take TARKA***

Take TARKA at the same time every day to avoid forgetting to take your TARKA dose.

If you do forget to take your TARKA tablet take it as soon as you remember, but only if you remember on the same day as the missed dose.

Never take two tablets to make up for the one you have missed.

### ***If you stop taking TARKA***

It is not recommended that you stop treatment with TARKA unless advised to do so by your doctor.

If you stop taking TARKA you may experience an increase in your blood pressure.

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

## ***4. POSSIBLE SIDE EFFECTS***

Like all medicines, TARKA tablets may cause side effects, although not everybody gets them. The side effects reported with TARKA are listed below:

Tell your doctor immediately and stop taking TARKA if you experience a severe allergic reaction causing an itchy rash and/or swelling of the face, lips, eyelids, tongue or throat. Although this is rare you may need urgent medical assistance.

**Common side effects (occur in 1 to 10 users in 100)**

- coughing
- dizziness, headache, feeling of spinning
- constipation
- a sudden sensation of warmth with redness over the body

**The following are Uncommon side effects (occur in 1 to 10 users in 1,000)**

- allergic reactions (such as rash or itching)
- drowsiness
- shaking/trembling
- awareness of your heartbeat (palpitations)
- fast or slow heart beats (AV-block)
- chest pain
- stomach and intestine problems
- nausea, stomach pain
- diarrhoea
- sweating
- abnormal liver function test
- frequent urination
- elevated fat lipid levels in the blood (hyperlipidaemia)

**The following are Rare side effects (occur in 1 to 10 users in 10,000)**

- loss of appetite
- fainting
- hair loss
- increase in the amount of bile pigment in the blood causing the skin or whites of the eyes to turn yellow (hyperbilirubinaemia)
- skin problems
- cold sores (herpes simplex)

**The following are Very Rare side effects (occur in less than 1 user in 10,000)**

- bronchitis (inflammation of the upper airways)
- sinus congestion (blocked or stuffy nose/sinuses)
- shortness of breath/tightness of the chest
- fatigue
- weakness
- aggression, anxiety, depression, agitation
- problems keeping your balance
- sleeping difficulties
- pins-and-needles feeling in your skin, hot/cold sensations
- taste changes
- vision problems (eg. blurred vision)
- yellowing of the skin or the whites of the eyes (jaundice)
- inflammation of the pancreas or liver
- vomiting
- blocked bile ducts
- dry mouth or throat
- severe allergic reaction causing swelling of the face, eyelids, tongue or throat

- changes in the levels of red or white blood cells which could lead to bruising, bleeding or reduced resistance to infection
- skin reactions including allergic reaction causing hives/ sores; skin inflammation, itchy rash, raised red patches, scaly or blistering rash
- muscle or joint pain, muscle weakness
- erectile dysfunction
- swelling of breasts (in males)
- severe heart problems/heart attack/fast heartbeat
- stroke
- sudden reduction in kidney function
- swelling caused by accumulation of fluid
- changes in blood potassium levels
- a sudden drop in blood flow through the body that may be life-threatening
- very low blood pressure
- low blood pressure when you stand or sit up
- changes in blood pressure

**The following are side effects with an unknown frequency:**

- a life threatening allergic reaction that causes a painful red or purple rash and blisters on the skin and lining of the mouth

Some side effects have not been seen with TARKA or its ingredients but have been seen with other medicines that are like TARKA:

- changes in numbers of red blood cells
- increased break down of red blood cells, which may cause fatigue
- confusion
- problem sleeping
- ringing in the ears
- abnormal heartbeat
- heart attack
- a brief disruption in the blood supply to part of the brain, which may cause a temporary disturbance in seeing, speaking or moving
- sinus infection or redness and swelling of the sinuses
- redness and swelling of the lining of the nose
- tongue infection or redness and swelling of the tongue
- a temporary narrowing of the airways in the lungs making it hard to breathe
- severe allergic reaction that affects the gut and causes belly pain (with or without nausea and vomiting) (intestinal angioedema)
- indigestion
- abnormal movement in the intestines, which may cause a swollen belly, stomach pain and constipation
- abnormal bile flow in the liver causing the whites of the eye to turn yellow
- a life threatening allergic reaction that causes the skin to blister and peel
- abnormal kidney function tests
- movement disorders such as extreme restlessness and disturbance of wanted or unwanted movements
- muscle weakness in both arms and both legs that affects your ability to move
- breasts that leak milk
- gums that spread over the teeth
- worsening of certain nerve and muscle disorders (such as myasthenia gravis, Lambert-Eaton syndrome, Duchenne muscular dystrophy)
- painful redness of the skin on the legs and arms
- greater than normal amounts of prolactin (female hormone) in the blood that causes the breasts to produce milk

This is not a complete list of side effects. Some effects may only be found with blood or other medical testing.

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### *5. HOW TO STORE TARKA*

Keep out of the reach and sight of children.

Do not use the eye drops after the expiry date which is stated on the overwrap of each unit and on the carton after the letters "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C. Do not freeze. Store in original package in order to protect from light.

Discard the bottle 28 days after opening, even if there is solution remaining.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.