

# TARKA®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using TARKA

TARKA contains the active ingredients trandolapril and verapamil hydrochloride. TARKA is used to treat hypertension (high blood pressure).

For more information, see Section [1. Why am I using TARKA](#) in the full CMI.

### 2. What should I know before I use TARKA

Do not use if you have ever had an allergic reaction to any medicine containing trandolapril (or any other ACE inhibitor), any medicine containing verapamil or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use TARKA](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with TARKA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use TARKA

- The usual dosage for TARKA is one tablet daily. The maximum dose of TARKA is one 4/240 mg tablet once daily.

More instructions can be found in Section [4. How do I use TARKA](#) in the full CMI.

### 5. What should I know while using TARKA

#### Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using TARKA.
- Have your blood pressure checked when your doctor says, to make sure TARKA is working for you

	<ul style="list-style-type: none"> <li>● If you feel light-headed or dizzy after taking your first dose of TARKA, or when your dose is increased, tell your doctor immediately.</li> <li>● Tell your doctor if you have excessive vomiting and/or diarrhoea while taking TARKA.</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>● Do not take eat grapefruit or drink grapefruit juice whilst taking TARKA.</li> <li>● Do not use TARKA to treat any other complaints unless your doctor or pharmacist tells you to.</li> <li>● Do not give this medicine to anyone else, even if they have the same condition as you.</li> <li>● Do not stop taking TARKA, or lower the dosage, without checking with your doctor.</li> </ul>

<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>● TARKA may cause dizziness, light-headedness, or tiredness, in some people. Make sure you know how you react to TARKA; and if you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.</li> </ul>
<p><b>Drinking alcohol</b></p>	<ul style="list-style-type: none"> <li>● Avoid drinking alcohol while you are taking this medicine. You may experience greater blood pressure lowering effects than usual. You may experience worsening dizziness or light-headedness.</li> </ul>
<p><b>Looking after your medicine</b></p>	<ul style="list-style-type: none"> <li>● Keep your tablets in a cool dry place where the temperature stays below 25°C.</li> </ul>

For more information, see Section [5. What should I know while using TARKA?](#) in the full CMI.

## 6. Are there any side effects?

Tell your doctor if the following worry you: dizziness, nausea, vomiting, diarrhoea, indigestion, persistent dry cough, headache, unusual tiredness, aching, tender or weak muscles and taste disturbance.

Tell your doctor immediately or go to your nearest hospital if you experience any serious side effects.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# TARKA®

**Active ingredient(s):** *trandolapril/verapamil hydrochloride*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using TARKA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TARKA.**

**Where to find information in this leaflet:**

- [1. Why am I using TARKA](#)
- [2. What should I know before I use TARKA](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use TARKA](#)
- [5. What should I know while using TARKA](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using TARKA

**TARKA contains two different types of medicines: verapamil hydrochloride in a slow release formulation, and trandolapril in an immediate release formulation.**

- Verapamil belongs to a group of medicines called calcium channel blockers.

Calcium channel blockers work by opening up blood vessels, which lets more blood and oxygen reach the heart and at the same time lowers high blood pressure.

- Trandolapril belongs to a group of medicines called Angiotensin Converting Enzyme (ACE) Inhibitors.

ACE inhibitors work by relaxing your blood vessels, making it easier for blood to move around your body. This helps lower blood pressure and increase the supply of blood and oxygen to your heart.

### **TARKA is used to treat hypertension (high blood pressure).**

There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems. You may feel fine and have no symptoms, but eventually hypertension can lead to serious health problems, including stroke, heart disease and kidney failure.

### **Ask your doctor if you have any questions about why TARKA has been prescribed for you.**

Your doctor may have prescribed it for another reason.

There is no evidence that TARKA is addictive.

TARKA should not be given to children under the age of 18, as there have been no studies of its effects in children.

## 2. What should I know before I use TARKA

### Warnings

#### Do not use TARKA if:

- you have an allergy to:
  - any medicine containing trandolapril (or any other ACE inhibitor)
  - any medicine containing verapamil.
  - any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

- you have experienced symptoms such as wheezing, swelling of the face, lips, mouth, tongue, throat, hands or feet, intense itching or severe skin rashes with previous ACE inhibitor treatment or if you or a member of your family have had these symptoms either spontaneously, or in response to another medicine in the past (a condition called angioedema).

Taking TARKA could cause this problem to happen again.

- you are pregnant or planning to become pregnant.  
It may affect your developing baby if you take it during pregnancy.



- you are breastfeeding

The active ingredients in TARKA may pass into breast milk and there is a possibility that your baby may be affected.

- you have severe kidney or liver problems
- you have certain heart conditions (such as heart failure, a very slow heart rate, heart conduction problems, some irregular heartbeats, or disease of the heart muscle)
- you have low blood pressure, (hypotension)
- you are currently being treated with intravenous  $\beta$ -adrenoreceptor antagonists (with the exception of being treated in ICU)
- you undergo treatments where your blood is treated outside your body (extracorporeal treatments), such as haemodialysis with certain membranes, or LDL-apheresis (removal of LDL from your blood)
- you have a history of angioedema (if you or a member of your family have had wheezing, swelling of the face, lips, mouth, tongue, throat, hands or feet, intense itching or severe skin rashes, either spontaneously, with previous ACE inhibitor treatment or in response to another medicine in the past)
- you are taking any of the following medications, or medications containing these ingredients:
  - aliskiren (under certain conditions)
  - ivabradine
  - Direct Oral Anticoagulants (DOACs) which thin the blood such as dabigatran (under certain conditions)

- neutral endopeptidase (NEP) inhibitors such as sacubitril or racecadotril.
- sacubitril in combination with valsartan

**Do not give this TARKA to a child under the age of 18 years.**

TARKA's safety and effectiveness in children younger than 18 years have not been established.

### **Tell your doctor if you:**

- have allergies to any other medicines, foods, preservatives or dyes.
- have or have had any of the following medical conditions:
  - any other heart problem, including aortic stenosis (narrowing of your aortic valve or aorta - the main artery leaving your heart)
  - blood vessel (circulatory) disease or a stroke
  - liver problems
  - kidney problems, including narrowing of the arteries to your kidneys (called renal artery stenosis) or need dialysis
  - high levels of potassium in your blood
  - recent vomiting or diarrhoea or if you are dehydrated
  - muscle conditions such as Duchenne muscular dystrophy, myasthenia gravis, Lambert-Eaton syndrome
  - connective tissue disease
  - dizzy spells
  - diabetes

- are of African origin, you may have a higher risk of angioedema.

In black patients, ACE inhibitors are less effective in lowering blood pressure than in white patients.

- are taking a diuretic ('fluid' tablets), potassium supplements, on a low-salt diet, or use potassium-salt substitutes.
- have or are about to have:
  - surgery or general anaesthetic
  - desensitisation treatment for an allergy e.g. to insect stings
  - regular dialysis, blood filtration or similar procedures
  - LDL removed from your blood (LDL-apheresis)
- have an intolerance to some sugars. TARKA contains sugars (as lactose).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor can discuss with you the risks and benefits involved.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with TARKA and affect how it works.** Please tell your doctor if you are taking any of the following:

- Medicines used to treat heart problems or high blood pressure:
  - Beta-blockers e.g. atenolol, propranolol, metoprolol, etc
  - Diuretics (also called fluid tablets)
  - Angiotensin II receptor blockers (also called ARBs, A2RAs, or sartans)
  - Aliskiren
  - Ivabradine
  - Digoxin
  - neutral endopeptidase (NEP) inhibitors such as sacubitril or racecadotril
  - Any other medicines used to control an irregular heartbeat e.g. quinidine, flecainide, amiodarone, disopyramide, procainamide
  - Any other medicines used to control high blood pressure
- Medicines used to treat or prevent blood clots (sometimes referred to as "blood thinners")

- Direct Oral Anticoagulants (DOACs) which thin the blood such as dabigatran
- aspirin, heparin
- Medicines used to lower cholesterol
  - Statins such as atorvastatin, simvastatin or lovastatin
- Medicines used to treat or prevent gout
  - Colchicine, sulfapyrazone, allopurinol
- Medicines used to lower blood glucose:
  - Anti-diabetic medicines such as insulin and any oral hypoglycaemic medicines, including metformin, glibenclamide or vildagliptin
- Medicines used to treat psychological problems
  - Any medicines used to treat depression, anxiety, or psychosis; such as imipramine, buspirone, midazolam, lithium or tricyclic antidepressants.
- Medicines used to treat epilepsy or seizures:
  - Phenytoin, carbamazepine, phenobarbital (phenobarbitone)
- Medicines used to treat or prevent organ transplant rejection (immunosuppressants):
  - Such as ciclosporin, everolimus, sirolimus, tacrolimus and temsirolimus
- Medicines used to treat infections or tuberculosis
  - Such as erythromycin, clarithromycin, telithromycin or rifampicin
  - Co-trimoxazole (trimethoprim and sulfamethoxazole)
- Medicines used in the treatment of Human Immunodeficiency Virus (HIV):

- Such as ritonavir
- Medicines used in surgical procedures such as:
  - General anaesthetics used for inducing sleep
  - Muscle relaxants, including dantrolene
- Medicines used to treat pain and inflammation (such as arthritis) or fever:
  - Non-steroidal anti-inflammatory drugs (NSAIDs) such as aspirin, ibuprofen, diclofenac, meloxicam, indometacin, celecoxib
  - Injectable gold
- Other medicines that may react with TARKA:
  - Potassium supplements, or large amounts of salt
  - Potassium - containing salt substitutes in your food (check the label)
  - Sympathomimetics - these may be found in some decongestants, cough / cold remedies and asthma medicines
  - Theophylline, a medicine used to treat asthma
  - Doxorubicin and cytostatic medicines, used to treat certain cancers
  - Cimetidine and other antacids, medicines commonly used to treat stomach ulcers and reflux
  - Neuromuscular blocking agents such as vecuronium

Avoid grapefruit juice, as this may increase the blood levels of verapamil.

This is not a complete list of medicines which may interfere with TARKA.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking TARKA. You may need to use different amounts of your medicine or take different medicines.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TARKA.**

## **4. How do I use TARKA**

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet. Your doctor will tell you how many tablets you will need to take each day and when to take them. This depends on your condition, and whether or not you are taking any other medicines.

**If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.**

### **How much to take**

- The usual dosage for TARKA is one tablet daily.
- The maximum dose of TARKA is one 4/240 mg tablet once daily.

### **When to take TARKA**

- Take TARKA at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

TARKA should ideally be taken in the morning with or after food.

- If you need to take an antacid, take it at least 2 hours before or 2 hours after your dose of TARKA.
- Continue taking your medicine for as long as your doctor or pharmacist tells you.

TARKA helps control your blood pressure, but it does not cure it.

## **How to take TARKA**

- Swallow the tablets whole with a full glass of water.
- Do not crush or chew TARKA tablets.

## **If you forget to use TARKA**

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

**Do not take a double dose to make up for the dose you missed.**

- This may increase the chance of getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.



If you have trouble remembering when to take your medicine, ask your pharmacist for advice.

## **If you use too much TARKA**

If you think that you have used too much TARKA, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

### **You should do this even if there are no signs of discomfort or poisoning.**

Symptoms of an overdose may include: a slow heartbeat, palpitations, chest pain, anxiety, feeling faint, dizzy or light-headed, and collapsing.

## **5. What should I know while using TARKA**

### **Things you should do**

- Have your blood pressure checked when your doctor says, to make sure TARKA is working for you.
- Drink plenty of water when you are using TARKA, especially if you sweat a lot (e.g. during hot weather or exercise).

If you do not drink enough water while taking TARKA, you may feel faint or light-headed or sick. This is because your blood pressure is dropping suddenly. If you continue to feel unwell, tell your doctor.

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking TARKA.
- Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.
- If you are going to have surgery, tell the surgeon that you are taking this medicine.
- Visit your doctor regularly so that they can check on your progress.

Your doctor may ask you to have blood tests to check your liver from time to time to make sure the medicine is working and to prevent unwanted side effects.

- If you are about to receive any dialysis, desensitisation treatment for an allergy e.g. to insect stings, or about to have LDL removed from your blood (LDL-apheresis), tell your doctor that you are taking this medicine.

### **Call your doctor straight away if you:**

- feel light-headed or dizzy after taking your first dose of TARKA, or when your dose is increased
- have excessive vomiting and/or diarrhoea while taking TARKA.

The loss of water and salt from your body may cause your blood pressure to drop too much.

- become pregnant while you are taking this medicine
- Remind any doctor, dentist or pharmacist you visit that you are using TARKA.

## **Things you should not do**

- Do not take eat grapefruit or drink grapefruit juice whilst taking TARKA.
- Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not stop taking TARKA, or lower the dosage, without checking with your doctor.

## **Things to be careful of**

**If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how TARKA affects you.**

TARKA may cause dizziness, light-headedness, or tiredness, in some people. Make sure you know how you react to TARKA; and if you have any of these symptoms,

do not drive, operate machinery or do anything else that could be dangerous.

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

**Avoid drinking alcohol while you are taking this medicine.**

You may experience greater blood pressure lowering effects than usual. You may experience worsening dizziness or light-headedness.

## **Looking after your medicine**

- Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the blister pack, they may not keep well.

- Keep your tablets in a cool dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

## **Getting rid of any unwanted medicine**

**If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

## **6. Are there any side effects?**

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking TARKA.**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

If you are over 65 years of age you may have an increased chance of getting side effects. Report any side effects to your doctor promptly.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

## Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>● persistent dry cough</li> <li>● taste disturbance</li> <li>● constipation</li> <li>● nausea, vomiting, diarrhoea or stomach upset/stomach pains</li> <li>● dizziness, light-headedness or vertigo</li> <li>● headache</li> <li>● unusual tiredness or weakness</li> <li>● aching, tender, or weak muscles not caused by exercise</li> <li>● flushing</li> <li>● excessive sweating</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> <p>This list includes the more common side effects of your medicine.</p>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>● slow, fast, or irregular heart beat</li> <li>● shortness of breath (sometimes with tiredness, weakness)</li> </ul>	<p><b>Tell your doctor straight away, if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>and reduced ability to exercise), which may occur together with swelling of the feet and legs due to fluid build up</p> <ul style="list-style-type: none"> <li>● fever, upper stomach pain, feeling generally unwell</li> <li>● symptoms of sunburn which may occur more quickly than normal, severe blisters, skin rash, itching or flaking skin</li> <li>● signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers</li> <li>● tremor</li> </ul>	<p>The above list includes serious side effects that may require medical attention. Serious side effects are rare.</p>

### **Very Serious side effects**

<b>Very Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing</li> </ul>	<p><b>Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of</b></p>

<b>Very Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● severe dizziness and confusion with visual disturbances and speech problems</li> <li>● rapid, shallow breathing, cold clammy skin, a rapid, weak pulse, dizziness, weakness and fainting</li> <li>● chest pain, fainting, collapse</li> </ul>	<p><b>these very serious side effects.</b></p> <p>This list includes very serious side effects. You may need urgent medical attention. These side effects are rare.</p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**



## 7. Product details

This medicine is only available with a doctor's prescription.

### What TARKA contains

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"><li>● TARKA 2/180 contains 2 mg of trandolapril and 180 mg of slow release verapamil hydrochloride as the active ingredients.</li><li>● TARKA 4/240 contains 4 mg of trandolapril and 240 mg of slow release verapamil hydrochloride as the active ingredients.</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>● microcrystalline cellulose</li><li>● docusate sodium</li><li>● hypromellose</li><li>● hypromellose</li><li>● iron oxide black</li><li>● iron oxide red</li><li>● iron oxide yellow</li><li>● lactose monohydrate</li><li>● macrogol 400</li></ul>

	<ul style="list-style-type: none"> <li>● macrogol 6000</li> <li>● magnesium stearate</li> <li>● povidone</li> <li>● colloidal anhydrous silica</li> <li>● sodium alginate</li> <li>● sodium stearyl fumarate</li> <li>● maize starch</li> <li>● purified talc</li> <li>● titanium dioxide</li> </ul>
<b>Potential allergens</b>	TARKA contains sugars as lactose.

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What TARKA looks like**

TARKA comes in two types of tablets:

TARKA 2/180 - pink, oval, film coated tablets, marked with the numbers "182" on one side. The 2/180 mg strength is available in boxes of 28 tablets. (AUST R 104663)

TARKA 4/240 - red-brown, oval, film coated tablets, marked with the numbers "244" on one side. The 4/240 mg strength is available in boxes of 28 tablets. (AUST R 104664)

## **Who distributes TARKA**

Viatrix Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatrix.com.au](http://www.viatrix.com.au)

Phone: 1800 274 276

This leaflet was prepared in October 2023.

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