

PART III: CONSUMER INFORMATION

PrTARKA[®]

trandolapril/verapamil hydrochloride sustained-release tablets

This leaflet is PART III of a three-part "Product Monograph" published when TARKA[®] was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about TARKA[®]. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

TARKA[®] lowers high blood pressure.

What it does:

TARKA[®] contains a combination of 2 drugs, trandolapril and verapamil hydrochloride:

- Trandolapril is an angiotensin converting enzyme (ACE) inhibitor. You can recognize ACE inhibitors because their medicinal ingredient ends in '-PRIL'. It lowers blood pressure.
- Verapamil hydrochloride is a calcium channel blocker. It changes the amount of calcium getting into the muscle cells of your heart and blood vessels. This can change the strength and speed at which your heart beats. It also opens up the blood vessels so that blood can be pumped around your body more easily. This helps to lower your blood pressure.

This medicine does not cure high blood pressure. It helps to control it. Therefore, it is important to continue taking TARKA[®] regularly even if you feel fine.

When it should not be used:

Do not take TARKA[®] if you:

- Are allergic to trandolapril, verapamil hydrochloride or to any non-medicinal ingredient in the formulation.
- Have experienced an allergic reaction (angioedema) with swelling of the hands, feet, or ankles, face, lips, tongue, throat, or sudden difficulty breathing or swallowing, to any ACE inhibitor or without a known cause. Be sure to tell your doctor, nurse, or pharmacist that this has happened to you.
- Have been diagnosed with hereditary angioedema: an increased risk of getting an allergic reaction that is passed down through families. This can be triggered by different factors, such as surgery, flu, or dental procedures.
- You have diabetes or kidney disease and are already taking a blood pressure-lowering medicine that contains aliskiren (such as Rasilez[®]) or an angiotensin II receptor blocker (ARB). You can recognize ARBs because the name of their medicinal ingredient ends in "-sartan".
- Are pregnant or intend to become pregnant. Taking TARKA[®]

during pregnancy can cause injury and even death to your baby.

- Are breastfeeding. TARKA[®] passes into breast milk.
- Have certain serious heart conditions.
- Have slow heartbeat or irregular heartbeat.
- Are on dialysis.
- Have liver cirrhosis (scarring of the liver).
- Have severe kidney disease.
- Are being given beta-blockers (heart medicine) by IV.
- Are less than 18 years old.
- You have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption

because lactose is a non-medicinal ingredient in TARKA[®].

What the medicinal ingredients are:

trandolapril and verapamil hydrochloride

What the non-medicinal ingredients are:

colloidal anhydrous silica, docusate sodium, ferric oxide, ferrous/ferric oxide, hydrated ferric oxide, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose monohydrate, macrogol 400, macrogol 6000, magnesium stearate, microcrystalline cellulose, povidone, purified water, sodium alginate, sodium stearyl fumarate, starch, talc, titanium dioxide.

What dosage forms it comes in:

TARKA[®] is available as sustained-release tablets in the following strength combinations of trandolapril/verapamil hydrochloride:

2 mg/240 mg; 4 mg/240 mg.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions – Pregnancy

- TARKA[®] should not be used during pregnancy. If you discover that you are pregnant while taking TARKA[®], stop the medication and contact your doctor, nurse, or pharmacist as soon as possible.

BEFORE you use TARKA[®] talk to your doctor, nurse or pharmacist if you:

- Are allergic to any drug used to lower blood pressure.
- Have recently received or are planning to get allergy shots for bee or wasp stings.
- Have narrowing of an artery or a heart valve.
- Have had a heart attack or stroke.
- Have heart failure.
- Have diabetes, liver, heart or kidney disease.

- Are dehydrated or suffer from excessive vomiting, diarrhea, or sweating.
- Are taking a salt substitute that contains potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of “water pill”).
- Are on a low-salt diet.
- Are taking a medicine that contains aliskiren, such as Rasilez[®], used to lower high blood pressure. The combination with TARKA[®] is not recommended.
- Are taking an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in “-SARTAN”.
- Are receiving gold (sodium aurothiomalate) injections.
- Have neuromuscular disease (myasthenia gravis, Lambert-Eaton syndrome or Duchenne muscular dystrophy).
- Have collagen vascular disease (Lupus, scleroderma)

You may become sensitive to the sun while taking TARKA[®]. Exposure to sunlight should be minimized until you know how you respond.

If you are going to have surgery and will be given an anesthetic, be sure to tell your doctor or dentist that you are taking TARKA[®].

TARKA[®] contains sodium. If you are on a low-salt diet tell your doctor, nurse or pharmacist you are taking TARKA[®].

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to TARKA[®]. Dizziness, lightheadedness, or fainting can especially occur after the first dose and when the dose is increased.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with TARKA[®]:

- Agents increasing serum potassium, such as a salt substitute that contains potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of “water pill”).
- Allopurinol used to treat gout.
- Antidiabetic drugs, including insulin and oral medicines.
- Gold for the treatment of rheumatoid arthritis.
- Lithium used to treat bipolar disease.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen, naproxen, and celecoxib.
- Blood pressure-lowering drugs, such as beta-blockers (e.g. propranolol, metoprolol, atenolol, timolol, and intravenous beta-blockers), including diuretics (“water pills”), aliskiren-

- containing products (e.g. Rasilez[®]), or angiotensin receptor blockers (ARBs).
- drugs used for the treatment of abnormal heartbeats (arrhythmia) such as disopyramide, procainamide, flecainide, quinidine, prazosin, terazosin, digoxin, digitoxin;
- dabigatran (a blood thinner)
- antibiotics such as erythromycin, telithromycin, rifampicin;
- some drugs used to treat migraine headaches (e.g. almotriptan);
- some drugs used to treat epilepsy or other neurological conditions (e.g. carbamazepine, phenobarbital, phenytoin);
- some drugs used to treat stomach ulcers (e.g. cimetidine);
- some drugs used to treat certain forms of arthritis or gout (e.g. sulfipyrazone, allopurinol, colchicine);
- some drugs used to treat lung conditions such as asthma (e.g. theophylline);
- any of the group of medicines known as major tranquilizers, or antidepressants of the tricyclic group (e.g. lorazepam, imipramine);
- any of the group of medicines known as benzodiazepines or other anti-anxiety treatment (e.g. buspirone, midazolam);
- anti-cancer medications (e.g. cisplatin, doxorubicin);
- any medication that can affect your immune system (e.g. corticosteroids, cyclosporine, sirolimus, tacrolimus);
- any neuromuscular blocking agent (e.g. atracurium);
- some cholesterol lowering drugs (e.g., simvastatin, atorvastatin, lovastatin);
- some HIV-antiviral medication (e.g. ritonavir);
- alcohol;
- St. John’s Wort;
- low density lipoprotein apheresis (dextran sulphate);
- hymenoptera (bees, wasps) venom;
- inhalation anesthetics.

Grapefruit juice: You should not drink Grapefruit juice if you are taking TARKA[®].

PROPER USE OF THIS MEDICATION

Take TARKA[®] exactly as prescribed. It is recommended to take your dose at about the same time every day.

Usual Adult Dose:

Dosage must be individualized. Your doctor will adjust the individual amounts of trandolapril and verapamil hydrochloride. Once the proper doses are achieved, your doctor may switch you to TARKA[®], as it may be more convenient to take only one pill. TARKA[®] should be taken once-a-day at the same time every day.

The usual adult dose for verapamil hydrochloride monotherapy is 180 to 240 mg/day.

The usual maintenance dose for trandolapril monotherapy is 1 to 2 mg once daily. The recommended initial dose is 1 mg once daily.

Take TARKA[®] with food to help it work better. TARKA[®] sustained-release tablets should be swallowed whole. Do not divide, crush or chew TARKA[®].

Overdose:

If you think you have taken too much TARKA[®] contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take one tablet, take another as soon as you remember, unless it is almost time for your next dose. If it is, do not take the missed tablet at all.

Never double-up on a missed dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- dizziness
- drowsiness, fatigue, weakness, tiredness, difficulty in sleeping,
- cough, dry mouth,
- headache
- abdominal pain
- constipation, diarrhea
- feeling sick (nausea)
- nasal congestion,
- flushing of the face or neck,
- ache or pains in the joints of muscles,
- swollen ankles,
- mild skin rash or itching,
- tingling or pickling of the skin,
- hair loss,
- impotence,
- blurred vision,
- taste disturbance

If any of these affect you severely, tell your doctor, nurse or pharmacist.

TARKA[®] can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom/effect		Talk with your doctor, nurse or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Common	Low Blood Pressure: dizziness, fainting, lightheadedness May occur when you go from lying or sitting to standing up.	√		
	Increased levels of potassium in the blood: irregular heartbeat, muscle weakness and generally feeling unwell		√	
Uncommon	Chest pain, faint pulse, irregular heartbeats, shortness of breath			√
	Fever and chills	√		
	Angioedema and Severe Allergic Reactions: swelling of the face, eyes, or tongue, difficulty swallowing, wheezing, hives and generalized itching, rash, fever, abdominal cramps, chest discomfort or tightness, difficulty breathing, unconsciousness.			√
	Kidney Disorder: change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue		√	
	Liver Disorder (Jaundice): yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect	Talk with your doctor, nurse or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Electrolyte Imbalance: weakness, drowsiness, muscle pain or cramps, irregular heartbeat		√	
Rare Decreased Platelets: bruising, bleeding, fatigue and weakness		√	
Decreased White Blood Cells: infections, fatigue, fever, aches, pains, and flu-like symptoms		√	
Unknown Ileus (blocked intestines): abdominal discomfort, constipation, nausea and vomiting, especially after meals excessive burping	√		
Seizures: fits with uncontrolled movements			√
Bronchospasm: Sudden worsening of shortness of breath and wheezing			√

This is not a complete list of side effects. For any unexpected effects while taking TARKA[®], contact your doctor or pharmacist.

HOW TO STORE IT

Keep TARKA[®] and all other medicines out of reach and sight of children.

TARKA[®] sustained-release tablets should be stored at 15° to 25°C, protected from light and moisture.

Do not take your tablets after the expiry date shown on the label.

It is important to keep the TARKA[®] sustained-release tablets in the original package.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report on line at:
www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect[™] Canada Web site at <http://www.healthcanada.gc.ca/medeffect>

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

The most recent version of this document plus the full Product Monograph, prepared for health professionals can be found at:

www.mylan.ca

or by contacting the sponsor, BGP Pharma ULC, Etobicoke, Ontario, M8Z 2S6 at:
1-844-596-9526

This leaflet was prepared by BGP Pharma ULC.

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