

PART III: CONSUMER INFORMATION

TARKA[®]

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[®] is used to treat hypertension (high blood pressure)

What it does:

TARKA[®] contains two different types of medicines: a calcium channel blocker and an Angiotensin Converting Enzyme (ACE) inhibitor.

Calcium channel blockers change 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.

ACE inhibitors also work by widening blood vessels, so helping to lower your blood pressure.

When it should not be used:

TARKA[®] should not be used if:

- you are allergic to any component of TARKA[®], including medicinal ingredients and non-medicinal ingredients;
- you have a history of angioedema (disfiguring type of temporary swelling which can be hazardous. See **SERIOUS SIDE EFFECTS**);
- you are pregnant or breast-feeding;
- you have certain serious heart conditions or
- you have slow heartbeat or irregular heartbeat.

Ask your doctor for advice.

What the medicinal ingredient is:

TARKA[®] contains the ACE inhibitor trandolapril and the calcium channel blocker verapamil hydrochloride. The tablet consists of two layers, one layer containing trandolapril, and the other layer containing verapamil hydrochloride in a sustained-release matrix.

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

- TARKA[®] should not be used during pregnancy. If you discover that you are pregnant or if you are planning to become pregnant while taking TARKA[®], stop the medication and contact your physician as soon as possible.

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

- you are taking salt substitutes or foods containing potassium. You should not be taking salt substitutes or foods containing potassium without the advice of your doctor;
- you have other medical problems, especially if you have diabetes, liver disease, kidney disease, heart or blood vessel disease;
- you are pregnant, breast-feeding or thinking of becoming pregnant. Taking TARKA[®] during pregnancy can cause injury and even death to your baby. This medicine should not be used during pregnancy. If you become pregnant while taking TARKA[®], stop the medication and report to your doctor as soon as possible. It is possible that TARKA[®] passes into breast milk. You should not breast-feed while taking TARKA[®]. If you need to keep breast-feeding, talk to your doctor about taking a different medicine to control your blood pressure;
- you are currently taking other medications. This is especially important if you are taking diuretics (water pills) which may add to the blood pressure lowering effect of TARKA[®];
- you are taking beta-blockers;
- you have neuromuscular disease (myasthenia gravis, Lambert-Eaton syndrome or Duchenne muscular dystrophy);
- you have allergies to this drug or any of its ingredients; you have allergies to this drug or any of its ingredients;
- you are undergoing dialysis;
- you are being treated for other conditions by other doctors, keep them all informed of which medications you are taking. Some drugs may reduce the effectiveness of TARKA[®] or

conversely, TARKA[®] may reduce the effectiveness of other drugs;

- you have to undergo any dental or other surgery, inform the dentist or doctor in charge that you are taking this medication;
- you perform tasks which may require special attention (for example, driving an automobile or operating dangerous machinery). Almost all patients can, but you should not perform these tasks until you know how you tolerate your medicine.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with TARKA[®] include:

- drugs used for the treatment of high blood pressure (hypertension) such as beta-blockers (e.g. propranolol, metoprolol, atenolol, timolol);
- drugs used for the treatment of abnormal heartbeats (arrhythmia) such as disopyramide, procainamide, flecainide, quinidine, prazosin, terazosin, digoxin, digitoxin;
- water tablets (diuretics) (e.g. hydrochlorothiazide) and potassium supplements (e.g. potassium chloride);
- agents increasing serum potassium (potassium sparing diuretics);
- antibiotics such as erythromycin, telithromycin, rifampin;
- some drugs used to treat diabetes (e.g. glyburide);
- some drugs used to treat migraine headaches (e.g. almotriptan);
- some drugs used to treat epilepsy or other neurological conditions (e.g. carbamazepine, phenobarbital);
- some drugs used to treat stomach ulcers (e.g. cimetidine);
- some drugs used to treat certain forms of arthritis or gout (e.g. sulfapyrazone, 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);
- some drugs used to treat mood disorders (e.g. lithium);
- any of the group of medicines known as non-steroidal anti-inflammatory drugs (e.g. naproxen, acetylsalicylic acid);
- 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);
- grapefruit juice;
- alcohol;
- St. John's Wort;
- low density lipoprotein apheresis (dextran sulphate);
- hymenoptera (bees, wasps) venom;
- inhalation anesthetics.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines including natural health products, prescription and non-prescription medicines.

PROPER USE OF THIS MEDICATION

Usual 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:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

If you or someone you know accidentally takes more than the stated dose, tell your doctor or hospital how much was taken. Treat even small overdoses seriously.

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

Along with its needed effects, a medicine may cause some unwanted effects. These are referred to as "side effects". Although not all of these side effects may occur, if they do occur they may need medical attention.

The most common side effects with TARKA[®] are dry cough, constipation and mild dizziness. Other less common side effects may include headaches, feeling sick (nausea), dry mouth, hair loss, nasal congestion, flushing of the face or neck, ache or pains in the joints of muscles, tiredness, swollen ankles, mild skin rash or itching, tingling or pickling of the skin, difficulty in sleeping, impotence, diarrhea, blurred vision, taste disturbance, anaemia or low numbers of white blood cells.

If you are suffering from excessive sweating, vomiting or diarrhea, your blood pressure may drop too low. If you feel ill after you have started taking TARKA[®] tablet, or notice anything unusual or unexpected, tell your doctor or seek medical assistance.

TARKA[®] can cause changes to your blood values. Your doctor will monitor your blood test results.

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

Symptom/effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
	Only if severe	In all cases	
Jaundice Yellowing of the eyes and skin			✓
Dizziness, lightheadedness, fainting		✓	✓

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.

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

Symptom/effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
	Only if severe	In all cases	
Common Hypotension Fainting when the blood pressure is too low			✓
Uncommon Chest pain, faint pulse, irregular heartbeats, shortness of breath Fever and chills Allergic Reaction Swollen mouth, lips, tongue, eyes, extremities, throat or difficulty swallowing or breathing (signs of angioedema). Intestinal angioedema may also occur and is characterized by abdominal pain (with or without nausea or vomiting). If you notice swelling or feel pain in these areas, inform your doctor immediately. You should also inform your doctor if you have unexplained fever, rash or itching.		✓	✓
		✓	✓
		✓	✓

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 0701C
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

This document plus the full Product Monograph, prepared for health professionals can be found at:

<http://www.abbott.ca>

or by contacting the sponsor, Abbott Laboratories, Limited,
Saint-Laurent, Qc H4S 1Z1 at:
1-800-699-9948

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