

PART III: CONSUMER INFORMATION

PrMAVIK® Trandolapril Capsules

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

ABOUT THIS MEDICATION

What the medication is used for:

- MAVIK® is used to treat high blood pressure.
- MAVIK® is used to treat patients after a heart attack.

Managing your lifestyle:

The "lifestyle" part of your treatment is as important as your medication. By working as a team with your doctor, you can help reduce the risk of hypertension complications to maintain the style of life you are accustomed to.

Together, you and your doctor can determine how each of the following applies to you:

Alcohol: Avoid alcoholic beverages until you have discussed their use with your doctor. Alcohol consumption may alter your blood pressure and/or increase the possibility of dizziness or fainting.

Diet: Generally, avoid fatty foods and food that is high in salt or cholesterol. Do not use salt substitutes containing potassium unless you discuss with your doctor first.

Exercise: Exercise regularly. It will help to keep your weight down, make you feel more energetic and is a good way to deal with stress. If you are not exercising regularly, be sure to discuss a fitness plan with your doctor.

Smoking: Avoid it completely.

What it does:

MAVIK® is a medication that helps to control blood pressure. It prevents blood vessels from constricting and therefore reduces blood pressure. It is not, however, a cure.

Although you may not feel any symptoms for years, hypertension can lead to stroke, heart attack, kidney disease and other serious conditions.

But it takes more than just medication to reduce blood pressure. Discuss the risk factors, and how they apply to your lifestyle, with your doctor. You may have to modify some of your daily habits to

keep your blood pressure down.

Hypertension is the medical term for high blood pressure. When blood flows through the blood vessels it pushes against their walls, almost like water pushing against the sides of a hose. Blood pressure is like that "push". When blood pressure is high (like the water pressure in a hose when the nozzle is partially shut), damage can occur to the heart and blood vessels.

When it should not be used:

Do not take MAVIK® if:

- you are pregnant or planning to become pregnant.
- you are breastfeeding
- you are allergic to the drug or any non-medicinal ingredients (Refer to the subheading "**What the non-medicinal ingredients are**" for a complete listing).
- you have a history of angioedema (disfiguring type of temporary swelling which can be hazardous.). See (**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**).

What the medicinal ingredient is:

Trandolapril

What the non-medicinal ingredients are:

Erythrosine, gelatin, iron oxides and hydroxides, lactose, maize starch, povidone, sodium lauryl sulphate, sodium stearyl fumarate, titanium dioxide.

What dosage forms it comes in:

MAVIK® is available in 0.5 mg, 1.0 mg, 2.0 mg and 4.0 mg capsules.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

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

BEFORE you use MAVIK® 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 MAVIK[®] 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 MAVIK[®], stop the medication and report to your doctor as soon as possible. It is possible that MAVIK[®] passes into breast milk. You should not breast-feed while taking MAVIK[®]. If you need to keep breast-feeding, talk to your doctor about taking a different medicine to control your blood pressure

- You are possibly allergic to MAVIK[®], including any of its non-medicinal ingredients. (Refer to the subheading “**What the non-medicinal ingredients are**” for a complete listing).
- 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 MAVIK[®].
- 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.
- 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 MAVIK[®] or conversely, MAVIK[®] 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.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with MAVIK[®] includes:

- agents increasing serum potassium (potassium sparing diuretics such as spironolactone, triamterene or amiloride or potassium supplements);
- salt substitutes containing potassium;
- allopurinol, cytostatic, immunosuppressive agents, systemic corticosteroids or procainamide;
- antidepressants (medication used to control your depression);
- antidiabetic agents (medication used to control your blood glucose);
- low density lipoprotein apheresis (dextran sulphate);
- hymenoptera (bees, wasps) venom;
- antacids;
- diuretics (water tablets) (e.g., hydrochlorothiazide);
- digoxin;
- inhalation anesthetics;
- lithium;
- nifedipine SR;
- non-steroidal anti-inflammatory agents (NSAIDs);
- warfarin;
- alcohol.

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:

Most people with high blood pressure need to take only one MAVIK[®] capsule per day. You can take your medication with a meal, or if you prefer, on an empty stomach. It is important to take it at the same time every day as prescribed by your doctor.

Remember, hypertension is a long-term disease without short term symptoms. Just because you feel fine does not mean you can stop taking your medication. If you stop, serious complications of the disease may occur. Therefore, you should continue to take it regularly, as prescribed by your doctor.

With your first dose of MAVIK[®] your blood pressure may drop too low and you may experience a sensation of lightheadedness. Chances are that some of these side effects will disappear once your system becomes used to the medication. If they persist, discuss this with your doctor. Your medication may need to have the dose reduced or changed.

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 stated dose tell your doctor or hospital how much was taken and show them the capsules.

Overdose symptoms expected with drugs like MAVIK[®] include a severe drop in blood pressure, shock, stupor, and an abnormally slow heart beat.

Missed Dose:

If you forget to take one of your MAVIK[®] capsules, take one as soon as you remember, if you remember on the same day. If not, do not take your missed capsule at all. Simply wait until it is time for your next dose. Do not take two doses at once.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, MAVIK[®] can cause side effects. Along with its intended action, any medication, including MAVIK[®], may cause side effects. After you have started taking MAVIK[®], it is important that you tell your doctor at once about any unexplained symptom you might experience.

Frequent side effects include coughing and dizziness. Other occasional side effects include:

- Headache
- Flu-like symptoms such as sore throat, fever, malaise, muscle pain, rash
- Nausea, vomiting, diarrhea
- Fatigue
- Sensation of lightheadedness
- Abdominal pain
- Loss of appetite (anorexia)
- Sad mood (depression)

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 MAVIK® capsules, or notice anything unusual or unexpected, tell your doctor or seek medical assistance.

MAVIK® can cause changes to your blood values. Your doctor will monitor your blood tests 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	
Uncommon	Allergic Reactions 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.			✓
	Jaundice Yellowing of the eyes and skin			✓
Frequency Not Known	Abdominal Pain (with or without nausea or vomiting)		✓	

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

HOW TO STORE IT

Store MAVIK® between 15° and 25°C in original container. MAVIK® should not be stored beyond the date indicated on the container. Keep this drug out of the reach of children.

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	Hypersensitivity reactions Skin rash, skin eruption or other effect of the skin or eyes, itching or fever			✓
	Hypotension Fainting when the blood pressure is too low			✓
	Excess sweating, vomiting, diarrhea	✓		
	Irregular or skipped heart beats		✓	

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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