

PART III: CONSUMER INFORMATION

Pr MAVIK® Trandolapril Capsules

Read this carefully before you start taking MAVIK® and each time you get a refill. This leaflet is a summary and will not tell you everything about MAVIK®. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about MAVIK®.

ABOUT THIS MEDICATION

What the medication is used for:

MAVIK® is used to treat:

- High blood pressure.
- Patients after a heart attack.

Managing your lifestyle:

The "lifestyle" part of your treatment is as important as your medication. In collaboration with your doctor, you can help reduce the risk of high blood pressure complications to maintain the lifestyle you are accustomed to. To do this, your doctor may discuss changes to your alcohol consumption and your diet. Your doctor will also probably recommend regular exercise and to completely avoid smoking.

What it does:

MAVIK® is an angiotensin converting enzyme (ACE) inhibitor. You can recognize ACE inhibitors because their medicinal ingredient ends in '-PRIL'.

This medicine does not cure your disease. It helps to control it. Therefore, it is important to continue taking MAVIK® regularly even if you feel fine.

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

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 allergic to trandolapril or any non-medicinal ingredients.
- 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.
- Are taking Entresto® (sacubitril/valsartan), due to the increased risk of serious allergic reaction which causes swelling of the face or throat (angioedema) when taken with MAVIK®. You must wait at least 36 hours after your last dose of sacubitril/valsartan before taking MAVIK®.
- Are already taking a blood pressure-lowering medicine that contains aliskiren (such as Rasilez®), or an angiotensin receptor blocker (ARB) which is another medicine to treat your high blood pressure [you can recognize ARBs because their medicinal ingredient ends in "-SARTAN".]; or another ACE inhibitor **and** you have one of the following conditions:
 - diabetes;
 - kidney disease;
 - high potassium levels;
 - heart failure combined with low blood pressure.
- Have narrowing of the arteries to one or both kidneys (renal artery stenosis).
- Have hypotension (low blood pressure).
- Are pregnant or intend to become pregnant. Taking MAVIK® during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. MAVIK® passes into breast milk.
- Have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption
 Because lactose is a non-medicinal ingredient in MAVIK®.

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:

Capsules: 0.5 mg, 1 mg, 2 mg, and 4 mg.

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions -Pregnancy**

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 doctor, nurse, or pharmacist as soon as possible.

BEFORE you use MAVIK® talk to your doctor, nurse or pharmacist if you:

- Are taking salt substitutes or foods containing potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of “water pill”).
- Have diabetes, liver or kidney disease.
- Have narrowing of an artery or heart valve disease.
- Have had a heart attack or stroke.
- Have heart failure.
- Are on dialysis or LDL apheresis (a treatment to remove LDL cholesterol from the blood).
- Are dehydrated or suffer from excessive vomiting, diarrhea, or sweating.
- Are possibly allergic to MAVIK® (or any drug used to lower blood pressure), including any of its non-medicinal ingredients. (Refer to the subheading “**What the non-medicinal ingredients are**” for a complete listing).
- Have recently received or are planning to get allergy shots for bee or wasp stings.
- 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 MAVIK® is not recommended.
- Are taking an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in “-SARTAN”. The combination with MAVIK® is not recommended.
- Are taking an antibiotic containing trimethoprim and sulfamethoxazole.
- Are taking any of the following medicines, the risk of angioedema may be increased:
 - Medicines used to prevent organ transplant rejection (e.g. sirolimus) and for cancer (e.g. everolimus and temsirolimus).
 - Sitagliptin or other gliptins (to treat Type II diabetes)
 - neutral endopeptidase (NEP) inhibitors.
- Are receiving gold (sodium aurothiomalate) injections.
- Are less than 18 years old.
- Have lupus or scleroderma.

You may become sensitive to the sun while taking MAVIK®. 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 MAVIK®.

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to MAVIK®. 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 MAVIK®:

- Agents increasing serum potassium, such as a salt substitute that contains potassium, potassium supplements, a potassium-sparing diuretic (a specific kind of “water pill”; examples include spironolactone, triamterene or amiloride) or co-trimoxazole (trimethoprim/ sulfamethoxazole); cyclosporine, an immunosuppressant medicine used to prevent organ transplant rejection; and heparin, a medicine used to thin blood to prevent clots;
- Alcohol. It may cause low blood pressure, dizziness and fainting;
- Allopurinol, used to treat gout;
- Antacids;
- Antidepressants, used to control your depression;
- Antidiabetic agents, including insulin and oral medicines used to control your blood glucose;
- Bee or wasp venom found in allergy shots for bee or wasp stings;
- Blood pressure-lowering drugs, including diuretics (“water pills”, e.g., hydrochlorothiazide), aliskiren-containing products (e.g. Rasilez®), or angiotensin receptor blockers (ARBs);
- Corticosteroids used to treat joint pain and swelling;
- Cytostatic agents used to treat cancers;
- Dextran sulphate used in low density lipoprotein apheresis to remove cholesterol from the blood;
- Digoxin used to treat irregular heartbeats;
- Gold for the treatment of rheumatoid arthritis;
- Immunosuppressive agents used to prevent rejection of a transplanted organ or treat autoimmune diseases;
- Inhalation anesthetics;
- mTOR (mammalian target of rapamycin) inhibitor therapy used to lower the body’s ability to reject a transplant (e.g. sirolimus) or to treat certain types of cancer (e.g. temsirolimus, everolimus);
- Lithium used to treat bipolar disease;
- Nifedipine SR used to treat chest pain or lower blood pressure;
- Non-steroidal anti-inflammatory drugs (NSAIDs) used to reduce pain and swelling. Examples include ibuprofen, naproxen, celecoxib, and acetylsalicylic acid (aspirin) used in higher doses;

- Procainamide used to treat irregular heartbeats;
- Co-trimoxazole (trimethoprim/sulfamethoxazole);
- Neutral endopeptidase (NEP) inhibitors.

PROPER USE OF THIS MEDICATION

Usual Adult Dose:

Take MAVIK® exactly as prescribed. Dosage must be individualized. The recommended initial dose of MAVIK® is 1 mg once daily. The dose can be increased over time by your doctor, up to a maximum dose of 4 mg once daily. For patients with kidney or liver impairment, the recommended initial dose is 0.5 mg once daily.

It is recommended to take your dose at about the same time every day. You can take MAVIK® with a meal, or if you prefer, on an empty stomach.

With your first dose of MAVIK® your blood pressure may drop too low and you may experience a sensation of lightheadedness. This effect should disappear once your system becomes used to MAVIK®. If this effect persists, discuss this with your doctor. Your medication may need to have the dose reduced or changed.

Overdose:

If you think you (or someone you know) may have taken too much MAVIK®, contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms. Tell them how much you have 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 your dose of MAVIK®, take it as soon as you remember, if you remember on the same day. If not, do not take your missed dose at all. Simply wait until it is time for your next dose. Do not double dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, MAVIK® can 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 or weakness
- Rash
- Nausea, vomiting, diarrhea, abdominal pain, loss of appetite (anorexia)
- Fatigue
- Sensation of lightheadedness, confusion
- Sad mood (depression)
- Blurred vision
- Confusion
- Dermatitis
- Sinusitis and rhinitis

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

MAVIK® 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 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			✓
	Low blood pressure Fainting, dizziness, lightheadedness, may occur when you go from lying or sitting to standing up.	✓		
	Increased levels of potassium in the blood: Irregular or skipped heart beats, muscle weakness and generally feeling unwell		✓	
Uncommon	Allergic Reactions (angioedema) Swollen mouth, lips, tongue, eyes, extremities, throat or difficulty swallowing or breathing			✓

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Intestinal angioedema Abdominal pain that may become more severe after eating, nausea, vomiting, intestinal cramps			✓
Kidney Disorder: change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue		✓	
Jaundice (Liver Disorder) Yellowing of the eyes and skin, dark urine, abdominal pain, nausea, vomiting, loss of appetite			✓
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	Toxic Epidermal Necrolysis: Severe skin peeling, especially in mouth and eyes		✓
	Stevens-Johnson Syndrome: Blistering of the mucous membranes of the skin including mouth, lips, eyelids, and genitals		✓

This is not a complete list of side effects. For any unexpected effects while taking MAVIK®, contact your doctor, nurse, 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 reach and sight of children.**

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on [Adverse Reaction Reporting \(https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html\)](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. 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

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Entresto® and Rasilez® are products of Novartis Pharmaceuticals Canada Inc.