

CONSUMER INFORMATION
Product Monograph Part III

^{Pr}COVERSYL[®]
perindopril arginine
2.5 mg, 5 mg, and 10 mg tablets

Servier Canada Inc.

Submission Control No. 092251

The Consumer Information Section (Part III) of the Product Monograph for Coversyl[®] has been submitted by the drug sponsor and is attached for your information.

The attached version accompanied the Notice of Compliance issued on August 23, 2005 and does not necessarily reflect the most current information for the product.

For the most up-to-date product information, please consult your health care professional.

Due to the fact that the information originated with an organization that is not subject to the *Official Languages Act*, the document may only appear in the language in which it was written. Translations of the document are the responsibility of the sponsor involved.

PART III: CONSUMER INFORMATION

COVERSYL®
Perindopril arginine

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

ABOUT THIS MEDICATION

What the medication is used for:

Your doctor has prescribed Coversyl® to treat your hypertension. Hypertension is the medical term for high blood pressure.

When blood pressure flows through the blood vessels it pushes against their walls. This pressure helps get your blood all around the body. Your blood pressure may be different at different times of the day, depending on how busy or worried you are. You have high blood pressure when your blood pressure stays higher than is needed, even when you are calm or relaxed.

There are usually no symptoms of high blood pressure. When blood pressure is high, damage can occur to the heart and blood vessels. The only way of knowing that you have high blood pressure is to have your blood pressure checked on a regular basis.

You may be prescribed Coversyl® to treat heart failure. Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body. Heart failure may start off with no symptoms, but as the condition progresses, you may feel short of breath or may get tired easily after light physical activity such as walking. You may wake up short of breath at night.

What it does:

Coversyl® belongs to a class of medicines called ACE inhibitors. These work by widening the blood vessels, which makes it easier for your heart to pump blood through them.

When it should not be used:

Do not take Coversyl® if:

- you are pregnant or try to become pregnant,
- you are breastfeeding or plan to breast-feed,
- you have experienced swelling of the face, tongue, lips or throat either spontaneously or in response to another medicine in the past (This rare condition is known as angioedema),
- hypersensitive (allergic) to the active substance or any of the other ingredients of Coversyl® (See "What the important

nonmedicinal ingredients are").

Coversyl® is not intended for use in children and adolescents (under 18 years old).

What the medicinal ingredient is:

The active substance of Coversyl® is perindopril arginine.

What the important nonmedicinal ingredients are:

The nonmedicinal ingredients in the film-coated tablet are: glycerol, hydrophobic colloidal silica, hypromellose, lactose monohydrate, macrogol 6000, magnesium stearate, maltodextrin, sodium starch glycolate (type A), titanium dioxide, and for the 5mg and 10mg tablets, chlorophyllin (E141ii).

What dosage forms it comes in:

Coversyl® comes in film-coated tablets of 2.5mg, 5mg or 10mg.

WARNINGS AND PRECAUTIONS

BEFORE you use Coversyl® talk to your doctor or pharmacist if:

- if you suffer from kidney (renal) or liver (hepatic) disease,
- if you undergo surgery,
- if you are taking diuretics (drug used to treat high blood pressure),
- if you are taking vasodilators including nitrates (products that make the blood vessels become wider),
- if you are taking, have recently taken or intend to take any other medicines, even those not prescribed.

Be aware that excessive perspiration, dehydration and conditions such as diarrhea and vomiting can cause a drop in blood pressure and this may aggravate the side effects of Coversyl®, so consult your doctor when this occurs.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with Coversyl®, and that you should not be taking without the advice of your doctor, include:

- diuretics ('water tablets')
- lithium tablets
- potassium supplements or potassium containing medicine.

PROPER USE OF THIS MEDICATION

Usual dose (adult dosage):

Always follow your doctor's instructions about how to take Coversyl®. You should check with your doctor or pharmacist if you are not sure.

The recommended dose of Coversyl® to treat hypertension is one 5mg-tablet taken in the morning. In some cases, as prescribed by your doctor, the dose could be doubled to 10mg taken in the

morning in a single daily dose.

The recommended dose of Coversyl® to treat heart failure is one 2.5mg-tablet taken in the morning. In most cases, as prescribed by your doctor, the dose may be doubled to 5mg taken in the morning in a single daily dose.

Dosage should be adjusted at intervals of at least 2 to 4 weeks.

Do not stop taking your medicine without the advice of your doctor even if you feel better. If you stop, serious complications of the disease may occur.

Coversyl® is for oral use. Tablets should be swallowed whole with a glass of water, preferably in the morning before a meal.

Overdose:

If you suspect that you or someone else has taken more than the amount of Coversyl® prescribed by your doctor, contact your doctor immediately.

Missed Dose:

Do not take a double dose to make up for forgotten doses. Just carry on with the next dose at the usual time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, Coversyl® can have side effects.

Most side effects are mild or moderate and usually transient. The most common side effects reported with Coversyl® are: cough (often described as dry and irritating), headache, feeling tired or lethargic, feeling weak, dizziness, nausea. If you faint, discontinue the drug and contact your doctor.

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 call your doctor or pharmacist
		Only if severe	In all cases	
Common	feeling tired or lethargic dizziness nausea	✓ ✓ ✓		
Uncommon	Angioedema Liver problems Infection Allergic reactions		✓ ✓ ✓	✓

- Angiodema- swelling of the face, lips, tongue, throat, difficulties in breathing or swallowing.
- Infection- Any signs of infection may be signs of a blood disorder.
- Allergic- Viral-like symptoms such as fever, lack of energy,

muscle pain, rash, which may be signs of an allergic reaction.

- Liver- Symptoms of abdominal pain, nausea, vomiting, loss of appetite, jaundice (yellowing of eyes and skin), may be signs of liver problems.

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

HOW TO STORE IT

Keep out of reach or sight of children.

This medicinal product should be stored between 15°C-30°C.

Do not use after the expiry date stated on the carton and tube.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs . If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345

toll-free fax 866-678-6789

By email: cadtmp@hc-sc.gc.ca

By regular mail:

National AR Centre

Marketed Health Products Safety and Effectiveness

Information Division

Marketed Health Products Directorate

Tunney's Pasture, AL 0701C

Ottawa ON K1A 0K9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Servier Canada Inc., at: 1-800-363-6093

This leaflet was prepared by Servier Canada Inc.

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