

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

 **STROMECTOL™**
ivermectin tablets, USP

Read this carefully before you start taking **STROMECTOL™** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **STROMECTOL™**.

What is STROMECTOL™ used for?

STROMECTOL™ is used to treat infections caused by some parasites (worms).

How does STROMECTOL™ work?

STROMECTOL™ works by killing the developing worms.

What are the ingredients in STROMECTOL™?

Medicinal ingredient: ivermectin

Non-medicinal ingredients: microcrystalline cellulose, pregelatinized starch, butylhydroxyanisol, citric acid and magnesium stearate.

STROMECTOL™ comes in the following dosage forms:

Tablets, 3 mg

Do not use STROMECTOL™ if:

- you are allergic (hypersensitive) to ivermectin or any of the other ingredients of STROMECTOL™.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take STROMECTOL™. Talk about any health conditions or problems you may have, including if you:

- Live or have spent time in parts of Africa. Certain infections from this area, such as “Loa Loa” or “eye-worm”, may cause side effects while taking STROMECTOL™. See “What are possible side effects from using STROMECTOL™?”, below.
- Have a weak immune system. In this case, your doctor may order tests and request stool samples to monitor your infection.
- Are pregnant or might become pregnant
- Are breast-feeding or intend to breast-feed, STROMECTOL™ is passed into breast milk.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with STROMECTOL™:

- warfarin

How to take STROMECTOL™:

Always take STROMECTOL™ exactly as your doctor has told you.

Take the tablets by mouth with water on an empty stomach.

Usual dose:

The dose depends on your illness and your weight.

For Strongyloidiasis: One dose of 0.2 mg per kg of body weight.

For Onchocerciasis: 0.15 mg per kg of body weight every 3 – 12 months.

Overdose:

If you think you have taken too much STROMECTION[™], contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

STROMECTION[™] is a single dose treatment. If you did not take your dose at the prescribed time, take it as soon as possible with water on an empty stomach.

What are possible side effects from using STROMECTION[™]?

These are not all the possible side effects you may feel when taking STROMECTION[™]. If you experience any side effects not listed here, contact your healthcare professional.

Side effects:

- Changes in some laboratory tests (increase of liver enzymes, increase of bilirubin in blood, increase of eosinophils)
- Low blood pressure (hypotension). You may feel dizzy or light-headed when standing up
- Worsening of asthma.

The side effects below depend on what you are taking STROMECTION[™] for. They also depend on whether you have any other infections.

People with intestinal strongyloidiasis (anguillulosis) may have the following side effects:

- feeling unusually weak
- loss of appetite, stomach pain, constipation or diarrhoea
- feeling dizzy
- shaking or tremors.

People with a heavy infection of the worm “Loa loa” may have the following side effects:

- abnormal brain function
- neck and back pain
- bleeding in the whites of your eyes
- loss of control of your bladder or your bowels
- difficulty standing or walking
- mental status changes
- not responding to other people or going into a coma.
- seizure

People infected with the worm “Onchocerca volvulus” which causes river blindness may have the following side effects:

- joint or muscle pains
- swelling of lymph nodes
- swelling, especially of the face, hands, ankles or feet
- fast heart rate
- changes to your vision and other eye problems such as infection, redness or unusual feelings
- bleeding in the whites of your eyes or swelling of your eye lids
- headache

Serious Side Effects			
Symptoms / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Allergic Reaction with symptoms of: <ul style="list-style-type: none"> • Sudden fever • Skin reactions (such as rash or itching) or other serious skin reactions • difficulty breathing 		X	
Stevens-Johnson syndrome with symptoms of: <ul style="list-style-type: none"> • flu like symptoms • peeling skin • blisters and sores around your mouth 		X	
Liver problems (hepatitis) with symptoms of: <ul style="list-style-type: none"> • Yellowing of the skin • Stomach pain • Nausea or vomiting • Feeling confused • Feeling tired or sleepy 		X	

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) 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.

Storage:

Store at 15-30°C.

Keep out of reach and sight of children.

If you want more information about STROMEKTOL™:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); or the Merck Canada website www.merck.ca or by calling Merck Canada at 1-800-567-2594.

To report an adverse event related to STROMEKTOL™, please contact 1-800-567-2594.

This leaflet was prepared by Merck Canada Inc.

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