

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

## **STROMECTOL**<sup>®</sup>

ivermectin tablets, USP

Read this carefully before you start taking **STROMECTOL**<sup>®</sup> 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**<sup>®</sup>.

### **What is STROMECTOL**<sup>®</sup> **used for?**

**STROMECTOL**<sup>®</sup> is used to treat infections caused by some parasites (worms).

### **How does STROMECTOL**<sup>®</sup> **work?**

**STROMECTOL**<sup>®</sup> works by killing the developing worms.

### **What are the ingredients in STROMECTOL**<sup>®</sup>?

Medicinal ingredient: ivermectin

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

### **STROMECTOL**<sup>®</sup> **comes in the following dosage forms:**

Tablets, 3 mg

### **Do not use STROMECTOL**<sup>®</sup> **if:**

- you are allergic (hypersensitive) to ivermectin or any of the other ingredients of **STROMECTOL**<sup>®</sup>.

### **To help avoid side effects and ensure proper use, talk to your healthcare professional before you take STROMECTOL**<sup>®</sup>. **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**<sup>®</sup>. See “**What are possible side effects from using STROMECTOL**<sup>®</sup>?”, 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**<sup>®</sup> is passed into breast milk.

### **Other warnings you should know about:**

It is important to take **STROMECTOL**<sup>®</sup> as recommended by your doctor. Too much **STROMECTOL**<sup>®</sup> might decrease your ability to remain awake, aware, and oriented and could lead into a coma.

**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 STROMECTIONOL®:**

- warfarin

**How to take STROMECTIONOL®:**

- Always take STROMECTIONOL® 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, or a person you are caring for, have taken too much STROMECTIONOL®, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

STROMECTIONOL® 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 STROMECTIONOL®?**

These are not all the possible side effects you may have when taking STROMECTIONOL®. If you experience any side effects not listed here, tell 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
- Decreased alertness including coma.

The side effects below depend on what you are taking STROMECTIONOL® 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

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<b>NOT KNOWN</b>			
<b>Allergic Reaction with symptoms of:</b> <ul style="list-style-type: none"> <li>• sudden fever</li> <li>• skin reactions (such as rash or itching) or other serious skin reactions</li> <li>• difficulty breathing</li> </ul>		x	
<b>VERY RARE</b>			
<b>Stevens-Johnson syndrome with symptoms of:</b> <ul style="list-style-type: none"> <li>• flu like symptoms</li> <li>• peeling skin</li> <li>• blisters and sores around your mouth</li> </ul>		x	
<b>Liver problems (hepatitis) with symptoms of:</b> <ul style="list-style-type: none"> <li>• yellowing of the skin</li> <li>• stomach pain</li> <li>• nausea or vomiting</li> <li>• feeling confused</li> <li>• feeling tired or sleepy</li> </ul>		x	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### 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>) 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: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website [www.merck.ca](http://www.merck.ca), or by calling 1-800-567-2594.

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