

STROMECTOL®

ivermectin
3 mg tablet

What is in this leaflet

This leaflet answers some common questions about STROMECTOL. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking STROMECTOL against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What STROMECTOL is used for

STROMECTOL is an antiparasitic medicine used to treat the following infection:

- Treatment of intestinal strongyloidiasis.
- Treatment of parasites in the blood or tissue caused by *Wuchereria bancrofti*.
- Treatment of human scabies after prior treatment has failed.

Intestinal Strongyloidiasis

Strongyloidiasis is an infection caused by the roundworm *Strongyloides stercoralis*. This tiny worm is barely visible to the naked eye. Exposure occurs when skin has direct contact with contaminated soil. Young roundworms penetrate the skin. They migrate through the bloodstream to the lungs and up the large airways. The worms are then swallowed, and the young worms mature and bury themselves into the intestinal wall. Adult roundworms begin producing eggs in the intestines.

Wuchereria bancrofti

This is a parasite that is carried and transmitted by the mosquito. It travels through the bloodstream and settles in the lymph and tissue of the patient, this can lead to fever and severe inflammation around the area the parasite has migrated to.

Human Scabies

Scabies is an infectious disease of the skin caused by a mite barely visible to the human eye called *Sarcoptes scabiei var hominis*. The mite burrows into the skin and causes a rash like reaction which can be very itchy and uncomfortable for the patient. Human scabies is almost always caught from another person by close contact.

How STROMECTOL works

STROMECTOL belongs to a group of medicines called an anthelmintic, these are medicines which bind to the nerve and muscle cells of parasites, resulting in their death.

Your doctor may have prescribed STROMECTOL for another reason. Ask your doctor if you have any questions about why STROMECTOL has been prescribed for you.

STROMECTOL is not addictive.

Before you take STROMECTOL

When you must not take it

Do not take STROMECTOL if:

- you have an allergy to STROMECTOL or any of the ingredients listed at the end of this leaflet
- the packaging is torn or shows signs of tampering
- the expiry date on the pack has passed. If you take this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start taking STROMECTOL, talk to your doctor.

Before you start to take it

Tell your doctor if:

- you are pregnant or intend to become pregnant.
If there is a need to consider using STROMECTOL during your pregnancy, your doctor will discuss with you the benefits and risks of using it.
- you are breast-feeding or plan to breast-feed.
Safety in breast feeding has not been established, you should discuss with your doctor whether you should stop breast-feeding.
- you have or have had any medical conditions, especially the following:
Loa loa
- you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell them before you take any STROMECTOL.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and STROMECTOL may interfere with each other. These include:

- diethylcarbamazine citrate (DEC) (a medicine used in the treatment of lymphatic filariasis)
- warfarin (a medicine used to prevent blood clots)

These medicines may be affected by STROMECTOL or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking STROMECTOL.

How to take STROMECTIONOL

How much to take

Take STROMECTIONOL only when prescribed by your doctor.

STROMECTIONOL is dosed according to the patient's weight, this may vary from patient to patient and the condition being treated.

Intestinal Strongyloidiasis

The recommended dose is one single oral dose of 200 micrograms per kilogram.

Wucheria Bancrofti

The recommended dose is one single oral dose every 6 months of 150-200 micrograms per kilogram.

For patients in endemic areas receiving treatment only once every 12 months, the recommended dose is 300-400 micrograms per kilogram.

Scabies

The recommended dose is one single oral dose of 200 micrograms per kilogram.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How to take it

STROMECTIONOL comes as tablets.

When taking the tablets, swallow them with a glass of water on an empty stomach. No food should be taken 2 hours before or two hours after administration.

In children less than 6 years, tablets should be crushed before swallowing.

If you are not sure about how to take STROMECTIONOL, talk to your doctor or pharmacist.

If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much STROMECTIONOL. Do this even if there are no signs of discomfort or poisoning.

Do not give STROMECTIONOL to anyone else, even if they have the same condition as you.

It is important to take the dose that your doctor prescribed. Decreased alertness including coma have been reported in patients with overdosage of STROMECTIONOL.

Adverse Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking STROMECTOL.

STROMECTOL may have unwanted adverse effects in a few people. Most often adverse effects are mild and transient, but they may be higher in patients infested with several parasites, particularly in the case of infection with *Loa loa*. In patients heavily infected with *Loa loa*, serious brain disorders have been reported rarely or very infrequently following treatment with STROMECTOL.

Decrease in alertness including coma have also been reported with the use of STROMECTOL.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice or have any of the following and they worry you:

- weakness
- abdominal pain
- loss of appetite
- diarrhoea
- nausea and/or vomiting
- constipation
- fatigue, feeling of being tired
- headache
- muscle and joint pain
- itching/rash possibly worsening of pre-existing scabies rash
- low blood pressure
- dizziness
- vertigo when standing
- difficulty standing or walking
- sweating
- testicular pain/discomfort
- redness of the eyes
- chills and/or fever
- sore throat
- tremor
- cough
- worsening of bronchial asthma
- seizures

If any of the following happen, contact your doctor immediately or go to Accident and Emergency at your nearest hospital:

- accelerated heart rate
- feeling of respiratory discomfort
- visual disturbance
- swelling of lymph nodes

Changes in some blood laboratory test results have been seen in patients whilst on treatment with STROMECTOL, if you have any concerns about your results discuss them with your doctor.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects. Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using STROMECTOL

Storage

Keep your tablets in the foil pack until it is time to take them. If you take the tablets out of the foil they may not keep well.

Keep STROMECTOL in a cool dry place where the temperature stays below 30°C. Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking STROMECTOL, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

STROMECTOL comes as a 3 mg tablet in a pack of 4 tablets:

- 3 mg tablet - A round white tablet marked with MSD on one side and 32 on the other.

Ingredients

Active ingredient:

STROMECTOL 3 mg tablet contains 3 mg ivermectin.

Inactive ingredients:

- microcrystalline cellulose
- pregelatinised corn starch
- butylated hydroxyanisole
- citric acid
- magnesium stearate

Manufacturer/Supplier

STROMECTOL is marketed in New Zealand by:

Merck Sharp & Dohme (New Zealand) Limited
P O Box 99 851
Newmarket
Auckland
NEW ZEALAND
Tel: 0800 500 673

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