

STROMECTOL®

Ivermectin

Consumer Medicine Information

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 used to treat river blindness (onchocerciasis) and threadworm involving the intestines (intestinal strongyloidiasis). These are caused by worm infections. In onchocerciasis the worm infection mainly affects the skin, glands (lymph nodes) and eyes. Changes to the skin may include an itchy rash, pale or dark patches, nodules (small lumps under the skin), thickening of the skin and/or loss of elasticity. The infection can cause enlarged glands in the neck, armpits or groin. The infection can also affect the eye and may cause conjunctivitis, a gritty or painful eye and may lead to blindness.

In the form of strongyloidiasis that is treated with STROMECTOL, the worm infection mainly affects the intestines and skin. Symptoms which may occur include itchy rash, vomiting, diarrhoea and stomach pain.

STROMECTOL works by killing the developing worms.

STROMECTOL is also used to treat scabies which is caused by the *Sarcoptes scabiei* mite.

Infection with the scabies mite causes discomfort and often intense itching of the skin, particularly at night, with irritating blisters or lumps on the skin. Classical sites of infestation are between the fingers, the wrists, underarm areas, female breasts (particularly the skin of the nipples), stomach area, penis, scrotum, and buttocks. Infants are usually affected on the face, scalp, palms and soles.

Scabies is usually spread person to person via direct skin contact, including sexual contact, though transfer via objects such as clothing or furnishings is also possible. Each person in contact with the infected person should seek treatment immediately. Note that the blisters or lumps on your skin may not go away immediately.

Bed linen and clothing should be washed in hot water, no bleaching is required. Shoes and other non washable items should be placed in a tightly sealed plastic bag for at least 3 days.

There are 2 types of scabies: typical scabies and crusted scabies (more severe).

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.

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**
- **you are pregnant, or intend to become pregnant**
Safety of the use of STROMECTOL in pregnancy has not been established.
- **the expiry date (EXP) printed 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 take STROMECTOL, talk to your doctor.

For the treatment of river blindness, do not give STROMECTOL to children under 5 years of age.

For this worm infection, the safety of STROMECTOL in children under 5 years of age has not been established.

For the treatment of strongyloidiasis, do not give STROMECTOL to children under 12 years of age.

For this worm infection, the effectiveness of STROMECTOL in

children under 12 years of age has not been established.

For the treatment of scabies, do not give STROMECTIONOL to children under 5 years of age or weighing less than 15 kg.

The safety of STROMECTIONOL in children under 5 years of age or less than 15 kg in weight has not been established.

Before you start to take it

Tell your doctor if:

- 1. if you are breast-feeding or plan to breast-feed.**
Your doctor will discuss the possible risks to your baby if you take STROMECTIONOL while you are breast-feeding.
- 2. you have or have had any medical conditions, especially:**

- liver disease

- 3. you have been treated for river blindness before.**

You may be more likely than others to experience serious side effects with STROMECTIONOL.

- 4. if 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 STROMECTIONOL.

Taking other medicines

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

Some medicines and STROMECTIONOL may interfere with each other. These include warfarin, used to prevent blood clots.

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

How to take STROMECTIONOL

How much to take

Your doctor will tell you how many tablets you need to take.

The dose depends on your infection and your weight or height. The dose usually ranges from one tablet to five tablets taken as a single dose.

For river blindness, you may need to take another dose in 6 to 12 months' time.

Depending on whether you have typical or crusted scabies, your doctor will decide the best treatment for you. The most common course of treatment is two doses, 8-15 days apart. STROMECTIONOL can be used alone or in combination with other treatments for scabies.

How to take it

Take STROMECTIONOL as a single dose with a full glass of water.

Always take STROMECTIONOL only as prescribed by your doctor.

If you take too much (overdose)

Immediately telephone your doctor or a Poisons Information Centre (telephone 13 11 26) if you think that you have or anyone else may have taken too much STROMECTIONOL. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too many tablets, you may experience some of the following:

- skin rash, hives;
- swelling of the legs, ankles or feet;
- headache, dizziness, feeling sleepy;
- loss of consciousness
- nausea, vomiting, diarrhoea; stomach pain
- dilated pupils of your eyes

- shortness of breath;
- walking unsteadily; decreased activity; shaking (or tremors); unusual weakness; tingling or numbness of the hands or feet; seizure.

While you are using STROMECTIONOL

Things you must do

Visit your doctor if scheduled, to check the progress of your infection.

This is to help make sure that the infection has cleared up completely. For threadworm, your doctor may do a follow-up examination of your stools.

For scabies, your doctor may take skin scrapings and check whether the number of mites has decreased. Your doctor may also take blood samples to monitor your liver function.

Things you must not do

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

Things to be careful of

Depressed level of consciousness and coma have been reported with the use of STROMECTIONOL

Be careful driving or operating machinery until you know how STROMECTIONOL affects you.

STROMECTIONOL may cause dizziness, light headedness, spinning sensation (vertigo), tremor, tiredness or sleepiness in some people. Make sure you know how you react to STROMECTIONOL before you drive a car, operate machinery or perform any other tasks that require you to be alert.

Side Effects

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

STROMECTIONOL helps most people with river blindness, threadworm or scabies, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

For river blindness:

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

- painful joints or muscles
- painful and tender glands in the neck, armpits or groin
- skin rash, itching or swelling
- fever
- lightheadedness or dizziness, especially when standing up
- worsening asthma
- headache
- swelling of the eyelids, conjunctivitis, a gritty or painful eye, redness of the eye, visual impairment
- swelling of the face, legs, ankles or feet
- fast heart beat

Some of these are symptoms of an allergic reaction which may occur as a result of the death of the worms after taking STROMECTIONOL for river blindness. They are usually not serious side effects.

For threadworm:

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

- unusual tiredness or weakness
- sleepiness
- dizziness

- nausea, vomiting, diarrhoea, constipation
- lack or loss of appetite
- stomach pain
- spinning sensation, also called vertigo
- shaking or tremors
- skin rash, itching or hives
- lightheadedness or dizziness, especially when standing up
- worsening asthma

These are usually not serious side effects.

For Scabies:

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

- tiredness
- stomach discomfort
- rash
- dizziness

The most common side-effects reported are due to the death of the mites and include headache, joint pain, loss of appetite and worsening of the itching.

For river blindness, threadworm or scabies:

If the following happen, tell your doctor immediately or go to accident and emergency at your nearest hospital:

- severe skin reaction which starts with painful red areas, then large blisters and ends with peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell.
- skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals

These are serious side effects. You may need urgent medical attention. These side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

If the patient has intestinal worms, ivermectin may kill the worms and patients may notice them being expelled during defaecation.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using STROMECTIONOL

Storage

Keep your tablets in the aluminium foil blister pack until it is time to take them.

If you take the tablets out of the box or aluminium foil blister pack they may not keep well.

Keep STROMECTIONOL in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicines 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 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

STROMECTIONOL is a white, round tablet with MSD marked on one side and 32 on the other side.

A pack contains 4 tablets.

Ingredients

Active ingredient:

STROMEKTOL contains ivermectin 3 mg per tablet.

Inactive ingredients:

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

STROMEKTOL does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

STROMEKTOL is supplied in Australia by:

Merck Sharp & Dohme (Australia)
Pty Limited
Level 1, Building A
26 Talavera Road
Macquarie Park NSW 2113
Australia

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