

STROMEKTOL®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using STROMEKTOL?

STROMEKTOL contains the active ingredient ivermectin. STROMEKTOL is used to treat river blindness (onchocerciasis), threadworm involving the intestines (intestinal strongyloidiasis) and scabies which is caused by the *Sarcoptes scabiei* mite.

For more information, see Section [1. Why am I using STROMEKTOL?](#) in the full CMI.

2. What should I know before I use STROMEKTOL?

Do not use if you have ever had an allergic reaction to Ivermectin or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use STROMEKTOL?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with STROMEKTOL and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use STROMEKTOL?

Your doctor will tell you how many tablets you need to take. The dose depends on your infection and your weight or height. Take STROMEKTOL as a single dose with a full glass of water.

More instructions can be found in Section [4. How do I use STROMEKTOL?](#) in the full CMI.

5. What should I know while using STROMEKTOL?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using STROMEKTOL. 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
Things you should not do	<ul style="list-style-type: none">Do not give STROMEKTOL to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">Be careful before you drive or use any machines or tools until you know how STROMEKTOL affects you
Looking after your medicine	<ul style="list-style-type: none">Keep your tablets in the aluminium foil blister pack until it is time to take them.Store it in a cool dry place (below 30°C) away from moisture, heat or sunlight

For more information, see Section [5. What should I know while using STROMEKTOL?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, STROMEKTOL can cause side effects, although not everybody gets them. Your doctor will discuss these with you and will explain the risks and benefits of using STROMEKTOL.

When you take STROMEKTOL, you can have some serious side effects.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

STROMEKTOL

Active ingredient: *Ivermectin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using STROMEKTOL.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using STROMEKTOL.

Where to find information in this leaflet:

- [1. Why am I using STROMEKTOL?](#)
- [2. What should I know before I use STROMEKTOL?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use STROMEKTOL?](#)
- [5. What should I know while using STROMEKTOL?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using STROMEKTOL?

STROMEKTOL contains the active ingredient Ivermectin. Ivermectin is derived from a class of antiparasitic agents called avermectins.

STROMEKTOL 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 STROMEKTOL, the worm infection mainly affects the intestines and skin. Symptoms which may occur include itchy rash, vomiting, diarrhoea and stomach pain.

STROMEKTOL works by killing the developing worms.

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

2. What should I know before I use STROMEKTOL?

Warnings

Do not use STROMEKTOL if:

- you are allergic to Ivermectin, or any of the ingredients listed at the end of this leaflet.**
Always check the ingredients to make sure you can use this medicine
- you are pregnant, or intend to become pregnant 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.

Check with your doctor if you:

- are breastfeeding or plan to breastfeed.**
- have or have had any medical conditions, especially:**
liver disease
- have been treated for river blindness before.**
You may be more likely than others to experience serious side effects with STROMEKTOL.
- 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 STROMEKTOL.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Safety of the use of STROMEKTOL in pregnancy has not been established.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will discuss the possible risks to your baby if you take STROMEKTOL while you are breastfeeding.

Paediatric

- For the treatment of river blindness, do not give STROMEKTOL to children under 5 years of age.**
For this worm infection, the safety of STROMEKTOL in children under 5 years of age has not been established.
- For the treatment of strongyloidiasis, do not give STROMEKTOL to children under 12 years of age.**

For this worm infection, the effectiveness of STROMECTION in children under 12 years of age has not been established.

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

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

3. What if I am taking other medicines?

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

Some medicines and STROMECTION 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 STROMECTION.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect STROMECTION.

4. How do I use STROMECTION?

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. STROMECTION can be used alone or in combination with other treatments for scabies.

How to take STROMECTION

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

Always take STROMECTION only as prescribed by your doctor.

If you use too much STROMECTION

If you think that you have used too much STROMECTION, 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.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using STROMECTION?

Things you should 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.

Remind any doctor, dentist or pharmacist you visit that you are using STROMECTION.

Things you should not do

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how STROMECTION affects you.

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

STROMECTION may cause dizziness, light headedness, spinning sensation (vertigo), tremor, tiredness or sleepiness in some people.

Make sure you know how you react to STROMECTION before you drive a car, operate machinery or perform any other tasks that require you to be alert.

Looking after your medicine

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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place (below 30°C) away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

A locked cupboard at least one and half metres above the ground is a good place to store medicines.

When to discard your medicine and how to get rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

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

STROMECTOL 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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects for patients being treated for river blindness

Less serious side effects	What to do
<p>Muscles and joint related</p> <ul style="list-style-type: none"> • painful joints or muscles <p>Skin related</p> <ul style="list-style-type: none"> • skin rash, itching or swelling <p>Lung related</p> <ul style="list-style-type: none"> • worsening asthma <p>Eye related</p> <ul style="list-style-type: none"> • swelling of the eyelids, conjunctivitis, a gritty or painful eye, redness of the eye, visual impairment <p>Heart related</p> <ul style="list-style-type: none"> • fast heart beat <p>Other</p> <ul style="list-style-type: none"> • painful and tender glands in the neck, armpits or groin • fever • light headedness or dizziness, especially when standing up • headache • swelling of the face, legs, ankles or feet <p>Some of these are symptoms of an allergic reaction which may occur as a result of the death of the worms after taking STROMECTOL for river blindness. They are usually not serious side effects.</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects for patients being treated for threadworm

Less serious side effects	What to do
<p>Gastrointestinal related</p> <ul style="list-style-type: none"> • nausea, vomiting, diarrhoea, constipation • lack or loss of appetite • stomach pain <p>Skin related</p> <ul style="list-style-type: none"> • skin rash, itching or hives <p>Lung related</p> <ul style="list-style-type: none"> • worsening asthma <p>Other</p> <ul style="list-style-type: none"> • unusual tiredness or weakness • sleepiness • dizziness • spinning sensation, also called vertigo • shaking or tremors • light headedness or dizziness, especially when standing up <p>These are usually not serious side effects.</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects for patients being treated for scabies

Less serious side effects	What to do
<p>Gastrointestinal related</p> <ul style="list-style-type: none"> • stomach discomfort <p>Skin related</p> <ul style="list-style-type: none"> • rash <p>Other</p> <ul style="list-style-type: none"> • tiredness • dizziness <p>The most common side effects reported are due to the death of the mites and include:</p> <ul style="list-style-type: none"> • headache • joint pain • loss of appetite • worsening of the itching. 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects for patients being treated for river blindness, threadworm or scabies

Serious side effects	What to do
<p>Allergic reaction related</p> <ul style="list-style-type: none"> • 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. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of</p>

Serious side effects	What to do
<ul style="list-style-type: none">• skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals <p>These are serious side effects. You may need urgent medical attention. These side effects are rare.</p>	these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What STROMEKTOL contains

Active ingredient (main ingredient)	ivermectin 3 mg per tablet
Other ingredients (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.

Do not take this medicine if you are allergic to any of these ingredients.

What STROMEKTOL looks like

STROMEKTOL is a white, round tablet with 'MSD' marked on one side and '32' on the other side (AUST R 181338).

A pack contains 4 tablets.

Who distributes STROMEKTOL

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

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