

Package leaflet: Information for the user**STROMEKTOL 3 mg tablets**
ivermectin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What STROMEKTOL is and what it is used for
2. What you need to know before you take STROMEKTOL
3. How to take STROMEKTOL
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1. What STROMEKTOL is and what it is used for

STROMEKTOL contains a medicine called ivermectin. This is a type of medicine which is used for infections caused by some parasites.

It is used to treat:

- an infection in your gut called intestinal strongyloidiasis (anguillulosis). This is caused by a type of round worm called “Strongyloides stercoralis”.
- an infection of your blood called microfilaremia due to “lymphatic filariasis”. This is caused by an immature worm called “Wuchereria bancrofti”. STROMEKTOL does not work against adult worms, only against immature worms.
- skin mites (scabies). This is when tiny mites burrow under your skin. This can cause severe itching. STROMEKTOL should only be taken when your doctor has proven or thinks you have scabies.

Stromectol will not stop you from getting one of these infections. It does not work against adult worms. Stromectol should only be taken when your doctor has proven or thinks you have a parasite infection.

2. What you need to know before you take STROMEKTOL**Do not take STROMEKTOL:**

- if you are allergic to ivermectin or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction to a medicine can include skin rash, difficulty breathing or fever.

Do not take STROMEKTOL if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking STROMEKTOL.

Warnings and precautions

Talk to your doctor before taking STROMEKTOL.

In particular, check with your doctor or pharmacist before taking your medicine if:

- you have a weak immune system.
- you live or have spent time in parts of Africa where people get infected with a type of worm called “Loa loa” - also called “eye-worm”.
- you live or have spent time in African areas. The use of DEC (diethylcarbamazine citrate) if you are infected with “Onchocerca volvulus” may result in increased risk of side effects which may sometimes be serious.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking STROMEKTOL.

Children

It is not known if it is safe to use STROMEKTOL in children who weigh under 15 kg.

Other medicines and STROMEKTOL

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

- Talk to your doctor straight away before taking STROMEKTOL if you are pregnant or might become pregnant. If you are pregnant, it should be taken only if clearly needed. You and your doctor will decide this.
- Talk to your doctor if you are breast-feeding or intend to breast-feed. This is because STROMEKTOL is passed into breast milk. Your doctor may decide to start your treatment one week after the birth of your child.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

You may feel dizzy, sleepy, shaky or like you are spinning after taking STROMEKTOL. If this happens, do not drive or use any tools or machines.

3. How to take STROMEKTOL

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth.
- For children less than 6 years of age, crush the tablets before swallowing.
- Take the number of tablets your doctor has prescribed all at the same time with water on an empty stomach. Do not eat any food within two hours before or after taking the tablets. This is because it is not known how food affects how your body absorbs the medicine.

How much to take

Treatment is a single dose.

- Take the number of tablets your doctor has prescribed all at the same time.
- The dose depends on your illness and your weight or your height.
- Your doctor will tell you how many tablets you need to take.

For intestinal strongyloidiasis (anguillulosis)

- The usual dose is:

BODY WEIGHT (kg)	DOSE (Number of 3 mg tablets)
15 to 24	One
25 to 35	Two
36 to 50	Three
51 to 65	Four
66 to 79	Five
≥ 80	Six

For **microfilaremia due to lymphatic filariasis** - caused by *Wuchereria bancrofti*

- The usual dose is:

BODY WEIGHT (kg)	DOSE when given once every 6 months	DOSE when given once every 12 months
	Number of 3 mg tablets	Number of 3 mg tablets
15 to 25	One	Two
26 to 44	Two	Four
45 to 64	Three	Six
65 to 84	Four	Eight

- This is repeated every 6 months or every 12 months.
- Alternatively and if no scales are available, the dosage may be determined by the patient's height, as follows:

HEIGHT (cm)	DOSE when given once every 6 months	DOSE when given once every 12 months
	Number of 3 mg tablets	Number of 3 mg tablets
90 to 119	One	Two
120 to 140	Two	Four
141 to 158	Three	Six
> 158	Four	Eight

For **scabies**

- Take a dose of 200 micro-grams for each kilogram of body weight.
- You will not know if the treatment has been fully successful for 4 weeks.
- Your doctor may decide to give you a second single dose within 8 to 15 days.

If you think that the effect of STROMEKTOL is too strong or too weak, talk to your doctor or pharmacist.

If you take more STROMEKTOL than you should

If you take more STROMEKTOL than you should, talk to a doctor straight away.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you forget to take STROMEKTOL

Try to take STROMEKTOL as prescribed. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Side effects are usually not serious and do not last long. They may be more likely to happen in people infected with several parasites. This is particularly true if they have the worm "Loa loa". The following side effects may happen with this medicine:

Allergic reactions

If you have an allergic reaction see a doctor straight away. The signs may include:

- sudden fever
- sudden skin reactions (such as rash or itching) or other serious skin reactions
- difficulty breathing.

See a doctor straight away if you notice any of the side effects above.

Other side effects:

- Liver disease (acute hepatitis).
- Changes in some laboratory tests (increase of liver enzymes, increase of bilirubin in blood, increase of eosinophils).
- Blood in urine.

The side effects below depend on what you are taking STROMEKTOL 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
- nausea or vomiting
- feeling sleepy or dizzy
- shaking or tremors.

Also, in intestinal strongyloidiasis (anguillulosis), adult round worms may be found in your stools.

People with microfilaremia due to lymphatic filariasis caused by Wuchereria bancrofti may have the following side effects:

- sweating or fever
- headache
- feeling unusually weak
- muscle, joint and general body pains
- loss of appetite, nausea
- pain in your stomach (abdominal and epigastric pain)
- cough or sore throat
- discomfort when breathing
- low blood pressure when getting or standing up - you may feel dizzy or light-headed
- chills
- dizziness
- pain or discomfort in your testicles.

People with scabies may have the following side effects:

- itching (pruritus) may get worse at the start of treatment. This does not usually last long.

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

- abnormal brain function
- neck or back pain
- bleeding in the whites of your eyes (also known as red eye)
- being short of breath
- loss of control of your bladder or your bowels
- difficulty standing or walking
- mental status changes
- feeling drowsy or confused
- not responding to other people or going into a coma.

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

- itching or rash
- joint or muscle pains
- fever
- nausea or vomiting
- swelling of lymph nodes
- swelling, especially of the hands, ankles or feet
- diarrhoea
- dizziness
- low blood pressure (hypotension). You may feel dizzy or light-headed when standing up
- fast heart rate
- headache or feeling tired
- 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
- asthma may get worse.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Bijwerkingen Centrum Lareb, website: www.lareb.nl. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store STROMEKTOL

Keep this medicine out of the sight and reach of children.

This medicine does not need any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What STROMEKTOL contains

- The active substance is ivermectin. Each tablet contains 3 mg of ivermectin.
- The other ingredients are microcrystalline cellulose, pregelatinized corn starch, butylhydroxyanisol, anhydrous citric acid and magnesium stearate.

What STROMEKTOL looks like and contents of the pack

STROMEKTOL 3 mg tablets are round, white, with the code '32' stamped on one side and 'MSD' on the other side.

The tablets are available in boxes containing blister strips with 1, 4, 10 or 20 tablets or a bottle containing 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Merck Sharp & Dohme BV
Waarderweg 39
2031 BN Haarlem
The Netherlands

RVG 28341

This medicinal product is authorised in the Member States of the EEA under the following names:

France, The Netherlands

STROMECTOL

This leaflet was last revised in September 2015.