

Package leaflet: information for the user  
IVERMECTIN SUBSTIPHARM 3 mg Tablets  
ivermectin

Read the entire 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.
- Do you have any further questions? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

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1. What is IVERMECTIN SUBSTIPHARM and what is this medicine used for?

IVERMECTIN SUBSTIPHARM contains a medicine called ivermectin. It is used against infections by certain parasites.

It is used for the treatment of:

- an infection in the gastrointestinal tract called intestinal strongyloidiasis (anguillulosis). This is caused by a type of roundworm called 'Strongyloides stercoralis'.
- an infection of the blood, called microfilaremia, as a result of 'lymphatic filariasis'. This is caused by an immature worm called 'Wuchereria bancrofti'. This medicine does not work against adult worms, only against immature worms.
- skin mites (scabies). Small mites burrow under your skin. This can cause severe itching. This medicine should only be used if your doctor determines or suspects that you have scabies.
- This medicine does not prevent you from getting any of these infections. It does not work against adult worms. This medicine should only be used if your doctor determines or suspects that you have a parasitic infection.

When should you not take this medicine or be extra careful with it?

2. When should you not take this medicine?

When should you not take this medicine?

- You have ever experienced severe skin rash or
- skin peeling, blistering and/or sores in the mouth after using ivermectin.

- Do not use this medicine if the above applies to you. If you are not sure, consult your doctor or pharmacist before taking this medicine.

When should you be extra careful with this medicine?

Contact your doctor before using this medicine.

Contact your doctor before using this medication.

Serious skin side effects have been reported in connection with ivermectin treatment, such as Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN). Stop using ivermectin and seek medical help immediately if you notice any of the symptoms described in section 4 that may indicate these serious skin side effects.

In particular, you should consult your doctor or pharmacist before using your medication if:

- you have a weak immune system you have lived in or spent time in African areas where people can become infected with a type of worm called 'Loa loa', also known as 'eye worm'.
- you have lived in or spent time in African areas.
- Use of DEC (diethylcarbamazine citrate) can increase the risk of, sometimes serious, side effects if you are infected with 'Onchocerca volvulus'.

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

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Children

Are you taking any other medicines?

Are you using any other medications?

Are you currently using any other medications alongside IVERMECTIN SUBSTIPHARM, have you done so recently, or do you plan to do so soon? that then your doctor or physician or pharmacist.

What should you pay attention to with food, drink and alcohol?

Not applicable.

Pregnancy and breastfeeding

- If you are pregnant or could become pregnant, tell your doctor immediately before taking this medicine. If you are pregnant, you should only take it if it is clearly necessary. You and your doctor will decide in consultation ..
- Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

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### Driving ability and the use of machines

You may feel dizzy, sleepy, shaky, or light-headed after using this medicine. If this happens, do not drive or use tools or machines.

### 3. How to take this medicine?

Always take this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

#### Take of this medicine

- Take this medicine by mouth.
- For children under six years, the tablets should be crushed before taking.
- Take the number of tablets prescribed by your doctor all at once with water on an empty stomach. Do not eat anything within two hours before or after taking the tablets. The reason for this is that it is not known how food affects how your body absorbs the medicine.

#### How much to take

The treatment consists of a single dose.

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

#### For intestinal strongyloidiasis (anguillulosis)

The usual dose is:

BODY WEIGHT (kg)	DOSAGE (number tablets 3 mg)
15 to 24	one
25 to 35	two
36 to 50	three
51 to 65	four
66 t/m 79	five
≥ 80	six

#### For microfilaremia due to lymphatic filariasis – caused by *Wuchereria bancrofti*

The usual dose is:

BODY WEIGHT (kg)	DOSE with semi-annual administration Number tablets 3 mg	DOSAGE at annual administration Number of tablets 3 mg
15 to 25	one	two
26 to 44	two	four
45 to 64	three	six
65 t/m 84	four	eight

This is repeated every 6 or every 12 months.

Alternatively, and if no scale is available, the dose can be calculated based on the patient's height as follows:

HEIGHT (cm)	DOSE at semi-annual administration Number tablets 3 mg	DOSE at annual administration Number of tablets 3 mg
90 to 119	one	two
120 to 140	two	four
141 to 158	three	six
> 158	four	eight

For scabies

- The dose is 200 micrograms per kg of body weight. Your doctor will tell you how many tablets you need to take.
- You will only know after 4 weeks if the treatment has been successful.
- Your doctor may decide to prescribe you a second single dose within 8 to 15 days.

If you think this medicine is too strong or not strong enough, consult your doctor or pharmacist.

Have you taken too much of this medicine?

Take exactly the dose of this medicine that your doctor has told you. Some patients experienced reduced consciousness or coma after taking too much of this medicine.

If you have taken too much of this medicine, contact a doctor immediately.

Have you forgotten to take this medicine?

Try to take this medicine according to the treatment prescription. Do not take a double dose to make up for the forgotten dose.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

#### 4. Possible side effects

Like any medicine, this medicine can have side effects. Not everyone gets them.

Stop using ivermectin and seek medical help immediately if you notice any of the following complaints:

- reddish, non-raised, disc-shaped or circular spots on the trunk, often with blisters in the center, skin peeling, sores in and around the mouth, throat, nose, or on the genitals and eyes; this severe skin rash may be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).

The side effects are usually not serious and do not last long. They are more common in people infected with various parasites. This is especially true if they have the worm 'Loa loa'. The following side effects may occur with this medicine:

Allergic reactions

If you experience an allergic reaction, contact a doctor immediately. Symptoms of this can include:

- sudden fever

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

If you notice any of the above side effects, contact a doctor immediately.

Other side effects:

- liver disease (acute hepatitis)
- changes in certain laboratory test results (increase in liver enzymes, bilirubin in the blood, or eosinophils)
- blood in the urine
- less consciousness or coma.

The side effects listed below depend on what you are using this medicine for. They also depend on whether you have other infections.

People with intestinal strongyloidiasis (anguillulosis) may experience the following side effects:

- feel unusually weak
- loss of appetite, stomach pain, constipation or diarrhea
- nausea or vomiting
- feel drowsy or dizzy
- tremors or chills.

Adult roundworms may also be found in your stool in cases of intestinal strongyloidiasis (anguillulosis).

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

- sweating or fever
- headache
- feeling unusually weak
- muscle and joint pain, general body pain
- loss of appetite, nausea
- pain in the stomach (abdomen and upper abdomen)
- cough or sore throat
- discomfort when breathing
- low blood pressure when getting up from bed or chair; you may feel dizzy or lightheaded
- cold chills
- dizziness
- pain or discomfort in the testicles.

People with scabies may experience the following side effects:

- itching may worsen at the start of treatment. This usually does not last long.

People with a heavy infection with the worm 'Loa loa' may experience the following side effects:

- abnormalities in brain function
- neck or back pain
- bleeding in the white of the eyes (also known as red eye)
- shortness of breath

- loss of control over the bladder or bowels
- difficult standing or walking
- psychological changes
- feeling drowsy or confused feeling
- not responding to other people or falling into a coma.

People infected with the worm 'Onchocerca volvulus' that causes river blindness may experience the following side effects:

- itching or rash
- pain in the joints or muscles
- fever
- nausea or vomiting
- swelling of the lymph nodes
- swelling, particularly of the hands, ankles, or feet
- diarrhea
- dizziness
- low blood pressure (hypotension). You may feel dizzy or lightheaded when standing up.
- rapid heartbeat
- headache or feel tired feeling
- changes in vision or other eye problems such as inflammation, redness, or unusual sensations
- bleeding in the whites of the eyes or swelling of the eyelids
- asthma can worse become.

The reporting of side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb, [www.lareb.nl](http://www.lareb.nl). By reporting side effects, you help us obtain more information about the safety of this medicine.

#### 5. How should you store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find it on the packaging after EXP. It includes a month and a year. The last day of that month is the expiry date.

Store below 25 °C.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed correctly and do not enter the environment.

#### 6. Contents of the packaging and other information

What substances are in this medicine?

- The active substance in this medicine is ivermectin.

- Each tablet contains 3 mg of ivermectin.
- The other substances in this medicine are:
- microcrystalline cellulose (E460), pregelatinized maize starch, butylated hydroxyanisole (E320), magnesium stearate (E470b).

What does IVERMECTIN SUBSTIPHARM look like and what is in a package?

This medicine is supplied as a round, white or almost white, flat beveled tablet. Box with 4, 8, 10, 12, 16, and 20 tablets.

It is possible that not all mentioned pack sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder:

SUBSTIPHARM

24 rue Erlanger

75016 Paris

France

For information and correspondence:

Eurocept BV Trappans 5

1244 RL Ankeveen

Netherlands

Manufacturer:

EUROPEENNE DE PHARMACOTECHNIE - EUROPHARTECH

Rue Henri Matisse

63370 Lempdes France

Registered as IVERMECTIN SUBSTIPHARM 3 mg Tablets - RVG 120488

This leaflet was last approved in August 2023