

Package leaflet: Information for the user

Ivermectine Orion 3 mg tabletten 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 Ivermectine Orion is and what it is used for
2. What you need to know before you take Ivermectine Orion
3. How to take Ivermectine Orion
4. Possible side effects
5. How to store Ivermectine Orion
6. Contents of the pack and other information

1. What Ivermectine Orion is and what it is used for

Ivermectine Orion 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*". Ivermectine Orion 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. Ivermectine Orion should only be taken when your doctor has proven or thinks you have scabies.

Ivermectine Orion will not stop you from getting one of these infections. It does not work against adult worms. Ivermectine Orion 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 Ivermectine Orion

Do not take Ivermectine Orion:

- 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.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking ivermectin.

Warnings and precautions

Talk to your doctor before taking Ivermectine Orion if:

- Serious skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported with ivermectin treatment. Stop using ivermectin and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.
- you have a **weak immune system**.
- you live or have **spent time in Africa**, especially areas where people can get infected with a type of worm called “*Loa loa*” - also called “eye-worm”.

Taking diethylcarbamazine citrate (DEC) with Ivermectin to treat a co-infection with the worm “*Onchocerca volvulus*” (which causes ‘river blindness’) may increase the risk of side effects which may sometimes be serious.

Children

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

Other medicines and Ivermectine Orion

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

Pregnancy and breast-feeding

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.

If you are pregnant, it should be taken only if clearly needed.

Ivermectin is passed into breast milk. Your doctor may decide to start your treatment one week after the birth of your child.

Driving and using machines

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

3. How to take Ivermectine Orion

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

How to take the tablets

- Take the tablets by mouth.
- For children less than 6 years of age, crush the tablets before swallowing.
- Take the tablets with water and 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 many tablets to take

- Treatment is a single dose.
- Your doctor will tell you how many tablets you need to take.
- Take all the tablets at the same time.
- The dose depends on your illness and your weight or your height.

For an infection in your gut called “intestinal strongyloidiasis” (anguillulosis)

- The usual dose is based on your body weight as follows:

Body weight (kg)	Dose (Number of tablets)
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15 to 24	One
25 to 35	Two
36 to 50	Three
51 to 65	Four
66 to 79	Five
≥80	Six

For an infection in your blood called “microfilaremia due to lymphatic filariasis

- The usual dose is based on your body weight as follows:

Body Weight (kg)	Dose when given once every 6 months Number of tablets	Dose when given once every 12 months Number of 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, if no weighing scales are available, the dosage may be determined by the patient’s height, as follows:

Height (cm)	Dose when given once every 6 months Number of tablets	Dose when given once every 12 months Number of tablets
90 to 119	One	Two
120 to 140	Two	Four
141 to 158	Three	Six
≥158	Four	Eight

For skin mites (scabies)

- Your doctor will prescribe a dose of 200 micrograms for each kilogram of your 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 take more Ivermectine Orion than you should

If you take more Ivermectine Orion than you should, talk to a doctor straight away. Decreased alertness including coma have been reported in patients taking too much ivermectin.

If you forget to take Ivermectine Orion

Take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

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

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.

Stop using Ivermectin and seek medical attention immediately if you notice any of the following symptoms:

reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of the mouth, throat, nose, genitals or eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).

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.
- Decrease in alertness including coma.

The side effects below depend on what you are taking the tablets for. They also depend on whether you have any other infections.

People with an infection in the gut called ‘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
- adult round worms may be found in your stools.

People with an infection in the blood called ‘microfilaremia’ due to lymphatic filariasis 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 skin mites (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 eyelids
- 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 national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ivermectine Orion

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

Aluminum/aluminum blister:

This medicine does not need any special temperature storage conditions. Store in the original package in order to protect from light.

PVC/PVDC blister:

Do not store above 25°C. Store in the original package in order to protect from light.

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 Ivermectine Orion contains

- The active substance is ivermectin. Each tablet contains 3 mg of ivermectin.
- The other ingredients are microcrystalline cellulose (E460), magnesium stearate (E470b), butyl hydroxyanisole (E320), anhydrous citric acid (E330), anhydrous colloidal silica (E551) and pregelatinized maize starch (E1422).

What Ivermectine Orion looks like and contents of the pack

Ivermectine Orion 3 mg tablets are round, approximately 5.60 mm in size, white to off-white, bevel edge tablets with “Y” on one side and 16 on other side.

The tablets are available in cartons containing blisters with 1 tablet, 4 tablets, 2 x 4 tablets, 6 tablets, 8 tablets, 10 tablets, 12 tablets, 16 tablets or 20 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

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In het register ingeschreven onder:

RVG 133481

This medicine is authorised in the Member States of the European Economic Area under the following names:

Nederland	Ivermectine Orion
Finland	Ivermectin Orion
Duitsland	Ivermectin Orion
Noorwegen	Ivermectin Orion

Deze bijsluiter is voor het laatst goedgekeurd in oktober 2024.