

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 the active substance ivermectin. This medicine is used for infections caused by some parasites.

Ivermectine Orion 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*".
- **skin mites (scabies)**. This is when tiny mites burrow under your skin. This can cause severe itching.

Ivermectine Orion will not stop you from getting one of these infections. Ivermectine Orion 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

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.

Tell your doctor, if you

- have a **weak immune system**.
- 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 a medicine called diethylcarbamazine citrate (DEC) with ivermectin to treat a co-infection ("river blindness") caused by a worm called "*Onchocerca volvulus*" may increase the risk of side effects which may sometimes be serious.

Children

Do not give this medicine to a child who weighs less than 15 kg because safety of ivermectin for them is not known.

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 (the number of tablets) depends on your illness and your weight or your height.

For an infection in your gut called “intestinal strongyloidiasis” (anguillulosis)
The usual dose (the number of tablets) is based on your body weight as follows:

Weight (kg)	Number of tablets
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 (the number of tablets) is based on your body weight as follows:

Weight (kg)	Number of tablets when given once every 6 months	Number of tablets when given once every 12 months
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 dose (the number of tablets) may be determined by the patient’s height, as follows:

Height (cm)	Number of tablets when given once every 6 months	Number of tablets when given once every 12 months
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, seek medical attention immediately. 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

- changes in some laboratory tests (increase in liver enzymes, bilirubin or eosinophils in blood)
- decrease in alertness including coma
- liver disease (acute hepatitis)
- blood in urine.

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

People with an infection in the gut called ‘intestinal strongyloidiasis’ (anguillulosis) may also have the following side effects:

- changes in some laboratory tests (decrease in the number of white blood cells [leukopenia] or of red blood cells [anaemia], increase in liver function test [alanine aminotransferase] or in liver enzyme [alkaline phosphatase])
- loss of appetite
- feeling sleepy, vertigo, shaking or tremors, dizziness
- stomach pain, constipation, diarrhoea, vomiting, nausea
- feeling unusually weak.

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

People with an infection in the blood called ‘microfilaremia’ due to lymphatic filariasis may also have the following side effects:

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

People with skin mites (scabies) may also 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 also have the following side effects:

- mental status changes
- abnormal brain function (even coma), confusion, not responding to other people, feeling drowsy, difficulty standing
- so called red eye (dilatation of blood vessels or bleeding in eye)
- being short of breath
- loss of control of bowels
- back or neck pain
- loss of control of bladder

- difficulty walking.

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

- so called red eye (bleeding in eye)
- symptoms of specific inflammatory reaction such as itching or rash, eye infection (conjunctivitis), joint or muscle pains, fever, swelling (especially of hands, ankles or feet), infection or swelling of lymph nodes, nausea, vomiting, diarrhoea, low blood pressure when getting or standing up (you may feel dizzy or light-headed), vertigo, fast heart rate, feeling unusually weak, headache
- unusual feeling in eyes, swelling of eyelids, several types of eye infections
- worsening of asthma.

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.

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

Aluminum/aluminum blister

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

PVC/PVDC/Al blister

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

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 ivermectin.
- The other ingredients are microcrystalline cellulose (E460), pregelatinised maize starch (E1422), magnesium stearate (E470b), anhydrous colloidal silica (E551), anhydrous citric acid (E330) and butylhydroxyanisole (E320).

What Ivermectine Orion looks like and contents of the pack

Ivermectine Orion is white to off-white, round, bevel edge tablet marked with “Y” on one side and “16” on other. The diameter is approximately 6 mm.

Pack sizes

1, 4, 6, 8, 8 (2 packs of 4), 10, 12, 16 or 20 tablets in blister pack.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Orion Corporation
Orionintie 1

FI-02200 Espoo
Finland

Manufacturer

Glenmark Pharmaceuticals s.r.o.
Fibichova 143
566 17 Vysoké Mýto
Tsjechië

Orion Corporation Orion Pharma
Orionintie 1
FI-02200 Espoo
Finland

Orion Corporation Orion Pharma
Joensuunkatu 7
FI-24100 Salo
Finland

In het register ingeschreven onder:
RVG 133481

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

Denemarken, Finland, Estland, Duitsland, Letland, Litouwen, Norwegen, Polen, Zweden: Ivermectin Orion
Nederland: Ivermectine Orion

Deze bijsluiter is voor het laatst goedgekeurd in mei 2026.