Package leaflet: Information for the user

Ivergalen 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 Ivergalen is and what it is used for

Ivergalen 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 microfilaraemia due to "lymphatic filariasis". This is caused by an immature worm called "Wuchereria bancrofti". Ivergalen 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. Ivergalen should only be taken when your doctor has proven or thinks you have scabies.

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

Do not take Ivergalen
- 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

In general, if you experience unusual symptoms that suddenly occur after taking any medicine, such as rash, hives or fever, you may assume that you are allergic to that medicine.

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

Warnings and precautions
Talk to your doctor or pharmacist before taking Ivergalen.
Serious skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported in association 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.

Before starting treatment with Ivergalen, tell your doctor about all your medical history. Tell your doctor

- if you have a weak immune system (immunity disorder)
- if you live or have lived in parts of Africa where there are cases of human parasitic infestation with the Loa loa filarial worm also called eye-worm
- if you currently live or have lived in parts of Africa.

Combined use of diethylcarbamazine citrate (DEC) to treat a co-infection with *Onchocerca volvulus* can lead to the risk of experiencing sometimes potentially severe side effects.

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

Ivergalen is not intended for use to prevent infestations with tropical parasites. It is not effective against adult parasitic worms and it may only be used on the advice of a doctor when parasitic infestation is certain or strongly suspected.

Children
The safety of using Ivergalen in children weighing less than 15 kg has not been evaluated.

Elderly patients
Clinical studies with ivermectin did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, treatment of an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Other medicines and Ivergalen
Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.
In general, you should seek advice from your doctor or pharmacist before taking any medicine.

Pregnancy, breast-feeding and fertility
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.

Ivergalen is excreted in human milk.

Driving and using machines
The effect of Ivergalen on the ability to drive and use machines has not been studied. In some patients the possibility of side effects such as dizziness, drowsiness, or feeling shaky or like you are spinning, which may affect the ability to drive or use machines, cannot be ruled out.
If you experience such symptoms, avoid driving or using machines.

3. How to take Ivergalen

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

Dosage

Treatment of gastrointestinal strongyloidiasis (anguillulosis)
The recommended dosage is 200 µg ivermectin per kg body weight, taken orally as a single dose.
For guidance, the dose based on body weight 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

Treatment of microfilaraemia caused by *Wuchereria bancrofti* (lymphatic filariasis)
The recommended dosage for mass treatment campaigns in *Wuchereria bancrofti* microfilaraemia (lymphatic filariasis) is approximately 150 to 200 µg ivermectin per kg body weight, taken as a single oral dose every 6 months.
In endemic areas where treatment can only be administered once every 12 months, the recommended dosage is 300 to 400 µg per kg body weight to maintain adequate suppression of microfilaraemia in treated patients.

For guidance, the dose based on body weight is:

BODY WEIGHT (kg)	DOSE administered every 6 months (number of 3 mg tablets)	DOSE administered every 12 months (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

Alternatively and in the absence of a set of weighing scales, the ivermectin dosage for administration in mass treatment campaigns can be determined by the patient's height, as follows:

HEIGHT (in cm)	DOSE administered every 6 months (number of 3 mg tablets)	DOSE administered every 12 months (number of 3 mg tablets)
90 to 119	one	two
120 to 140	two	four
141 to 158	three	six
> 158	four	eight

Treatment of human scabies

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

What else must you observe when you are treated for scabies
Everyone who comes into contact with you, especially members of your family and partners, should visit a doctor as soon as possible. The doctor will decide whether these persons should also be treated. If infected contact persons are not also treated promptly, there is a danger that they could re-infect you with scabies.

You should follow hygienic measures to prevent reinfection (i.e. keeping fingernails short and clean) and you should follow official recommendations regarding the cleaning of clothing and bedding closely.

If you have the impression that the effect of Ivergalen is too strong or too weak talk to your doctor or pharmacist.

Method of administration
Tablets for oral use.
Always follow the dosage stated by your doctor. If in doubt, consult your doctor or pharmacist.
In children under 6 years of age, the tablets should be crushed before swallowing.
Treatment consists of a single dose. The number of prescribed tablets should be taken all at the same time as a single dose. The tablets should be taken with some water on an empty stomach. Do not eat any food within two hours before or after taking this medicine. This is because it is not known how food affects the absorption of this medicine in the body.

If you take more Ivergalen than you should
Contact your doctor or pharmacist immediately.

If you forget to take Ivergalen
Always follow your doctor's prescription. Do not take a double dose to make up for a forgotten dose.
If you have any further questions on the use of this medicine, 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

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 on blood, increase of eosinophils)
- blood in urine
- decrease in alertness including coma

The side effects below depend on what you are taking Ivergalen 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
- a decrease in the number of white blood cells (leukopenia)
- a decrease in the amount of red blood cells or the red blood pigment haemoglobin (anaemia)

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

People with microfilaraemia 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 testicle

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 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

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 mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).

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 Ivergalen

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 pack. The expiry date refers to the last day of that month.

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

Do not throw away any medicines via wastewater. 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 Ivergalen contains

- The active substance is ivermectin.
  One tablet contains 3 mg ivermectin.
- The other ingredients are:
  Cellulose microcrystalline (E 460), pregelatinised maize starch, butylhydroxyanisole (E 320), magnesium stearate (E 470b).

What Ivergalen looks like and contents of the pack
This medicine is presented as a round, white or almost white, flat chamfered tablet.
Box of 4, 8, 10, 12, 16 and 20 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Galenicum Derma, S.L.
Ctra. N-1, Km 36,
28750 San Agustin de Guadalix (Madrid)
Spain

Manufacturer:
EUROPEENNE DE PHARMACOTECHNIE - EUROPHARTECH
Rue Henri Matisse
63370 Lempdes - France

Dit medicijn is in het register ingeschreven onder: Ivergalen 3 mg Tabletten - RVG 120488

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:
Nederland: Ivergalen 3 mg tabletten
Portugal: Ivergalen 3 mg comprimidos
Spanje: Ivergalen 3 mg comprimidos EFG

Deze bijsluiter is voor het laatst goedgekeurd in mei 2025.