

## **Bijsluiter: informatie voor de patiënt**

Ivermectine Sigillata 3 mg tabletten

**ivermectine**

**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 {{(INVENTED) NAME}} is and what it is used for
2. What you need to know before you take {{(INVENTED) NAME}}
3. How to take {{(INVENTED) NAME}}
4. Possible side effects
5. How to store {{(INVENTED) NAME}}
6. Contents of the pack and other information

### **1. What {{(INVENTED) NAME}} is and what it is used for**

{{(INVENTED) NAME}} 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 gastrointestinal 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*". {{(INVENTED) NAME}} 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. {{(INVENTED) NAME}} should only be taken when your doctor has proven or thinks you have scabies.

**{{(INVENTED) NAME}} will not stop you from getting one of these infections.** It does not work against adult worms. {{(INVENTED) NAME}} 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 {{(INVENTED) NAME}}**

#### **Do not take {{(INVENTED) NAME}}:**

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.

Do not take {{(INVENTED) NAME}} if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking {{(INVENTED) NAME}}.

## Warnings and precautions

Talk to your doctor or pharmacist before taking {(INVENTED) NAME}.

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.

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 diethylcarbamazine citrate (DEC) 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 {(INVENTED) NAME}.

## Children

It is not known if it is safe to use {(INVENTED) NAME} in children who weigh under 15 kg.

## 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 {(INVENTED) NAME}

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

## Pregnancy and breastfeeding

- Talk to your doctor straight away before taking {(INVENTED) NAME} 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 {(INVENTED) NAME} 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 {(INVENTED) NAME}. If this happens, do not drive or use any tools or machines.

## 3. How to take {(INVENTED) NAME}

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 gastrointestinal strongyloidiasis (anguillulosis):

The usual dose is:

<b>BODY WEIGHT (kg)</b>	<b>DOSE (Number of 3 mg tablets)</b>
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:

<b>BODY WEIGHT (kg)</b>	<b>DOSE when given once every 6 months Number of 3 mg tablets</b>	<b>DOSE when given once every 12 months Number of 3 mg tablets</b>
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 can be determined by the patients' height, as follows:

<b>HEIGHT (cm)</b>	<b>DOSE when given once every 6 months Number of 3 mg tablets</b>	<b>DOSE when given once every 12 months Number of 3 mg tablets</b>
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.

It corresponds to:

<b>BODY WEIGHT (kg)</b>	<b>DOSE (Number of 3 mg tablets)</b>
15 to 24	one
25 to 35	two
36 to 50	three
51 to 65	four
66 to 79	five
≥ 80	six

- 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 {(INVENTED) NAME} is too strong or too weak, talk to your doctor or pharmacist.

#### **If you take more {(INVENTED) NAME} than you should**

It is important to take the dose that your doctor prescribed. Decreased alertness including coma have been reported in patients with overdosage of ivermectin.

If you take more {(INVENTED) NAME} than you should, talk to a doctor straight away.

#### **If you forget to take {(INVENTED) NAME}**

Try to take {(INVENTED) NAME} as prescribed. 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.

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).

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 one type of white blood cell...).
- Blood in urine
- Decrease in alertness including coma.

The side effects below depend on what you are taking {(INVENTED) NAME} for. They also depend on whether you have any other infections.

**People with gastrointestinal 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 gastrointestinal 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, pharmacist or nurse. 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 {(INVENTED) NAME}**

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 after ‘EXP’. The expiry date refers to the last day of that month.

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 to protect the environment.

### **6. Contents of the pack and other information**

**What {(INVENTED) NAME} contains**

- The active substance is ivermectin. Each tablet contains 3 mg of ivermectin.  
The other ingredients are microcrystalline cellulose (E 460), pregelatinised corn starch, butylhydroxyanisole (E 320), anhydrous citric acid (E 330) and magnesium stearate (E 572).

**What {(INVENTED) NAME} looks like and contents of the pack**

{(INVENTED) NAME} are round, white with the code "A300" stamped on one side.

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

Not all of pack sizes may be marketed.

**Houder van de vergunning voor het in de handel brengen en fabrikant**

*Houder van de vergunning voor het in de handel brengen*

Sigillata Limited  
Inniscarra,  
Main Street,  
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Ierland

*Fabrikant*

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Hafnarfjörður IS-220  
IJsland

**In het register ingeschreven onder:**

RVG 118763

**Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:**

Nederland	Ivermectine Sigillata 3 mg tabletten
Duitsland	Ivermectin Sigillata 3 mg Tabletten
Frankrijk	Ivermectine Sigillata
Italië	SCAVER

**Deze bijsluiter is voor het laatst goedgekeurd in oktober 2023.**