

## Package leaflet: Information for the patient

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

#### 1. What Ivermectin Aristo tabletten is and what it is used for

Ivermectin Aristo tabletten 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*". Ivermectin Aristo tabletten 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. Ivermectin Aristo tabletten should only be taken when your doctor has proven or thinks you have scabies.

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

Ivermectin Aristo tabletten 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 Ivermectin Aristo tabletten

##### Do not take Ivermectin Aristo tabletten

- 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 Ivermectin Aristo tabletten if the above applies to you. If you are not sure talk to your doctor or pharmacist before taking Ivermectin Aristo tabletten.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Ivermectin Aristo tabletten.

Serious skin reactions including Steven-Johnson syndrome and toxic epidermal necrolysis, have been reported in association with ivermectin treatment. Stop using ivermectin and seek medicinal attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Before starting treatment with Ivermectin Aristo tabletten, tell your doctor about all your medical history. Tell your doctor, if you

- have a weak immune system (immunity disorder);
- are known to have an impaired barrier between your blood and your brain, caused by a dysfunction of a certain carrier protein (P-glycoprotein or P-gp);
- live or have lived in parts of Africa where there are cases of human parasitic infestation with *Loa loa* filarial worm as called eye-worm;
- currently live or have lived in parts of Africa.

Combined use of a medicine called 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 Ivermectin Aristo tabletten.

Ivermectin Aristo tabletten 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**

It is not known if it is safe to use Ivermectin Aristo tabletten 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 experiences 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 or concomitant disease or other drug therapy.

### **Other medicines and Ivermectin Aristo tabletten**

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 and breast-feeding**

#### Pregnancy

If you are pregnant, do not take Ivermectin Aristo tabletten unless your doctor has instructed you to. If you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### Breast-feeding

Ivermectin Aristo tabletten is excreted in human milk. If you are breast-feeding, tell your doctor and do not follow this treatment unless he/she has instructed you to.

Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

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

### 3. How to take ivermectin Aristo tabletten

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)

For guidance, the dose based on body weight is:

[for 3 mg only]

BODY WEIGHT (kg)	DOSE (number of 3 mg tablets)
15 to 24	1
25 to 35	2
36 to 50	3
51 to 65	4
66 to 79	5
≥ 80	6

[for 6 mg only]

BODY WEIGHT (kg)	DOSE (number of 6 mg tablets)
15 to 24	0.5
25 to 35	1
36 to 50	1.5
51 to 65	2
66 to 79	2.5
≥ 80	3

##### Treatment of microfilaraemia caused by *Wuchereria bancrofti* (lymphatic filariasis)

For guidance, the dose based on body weight is:

[for 3 mg only]

BODY WEIGHT (kg)	DOSE when given once every 6 months (number of 3 mg tablets)	DOSE when given once every 12 months (number of 3 mg tablets)
15 to 25	1	2
26 to 44	2	4
45 to 64	3	6
65 to 84	4	8

[for 6 mg only]

BODY WEIGHT (kg)	DOSE when given once every 6 months (number of 6 mg tablets)	DOSE when given once every 12 months (number of 6 mg tablets)
15 to 25	0.5	1
26 to 44	1	2
45 to 64	1.5	3
65 to 84	2	4

This is repeated every 6 months or every 12 months.

Alternatively and if no scales are available, the dose of ivermectin for use in mass chemotherapy campaigns may be determined by the patient's height as follows:

[for 3 mg only]

HEIGHT (cm)	DOSE when given once every 6 months (number of 3 mg tablets)	DOSE when given once every 12 months (number of 3 mg tablets)
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	tablets)	tablets)
90 to 119	1	2
120 to 140	2	4
141 to 158	3	6
> 158	4	8

[for 6 mg only]

HEIGHT (cm)	DOSE when given once every 6 months (number of 6 mg tablets)	DOSE when given once every 12 months (number of 6 mg tablets)
90 to 119	0.5	1
120 to 140	1	2
141 to 158	1.5	3
> 158	2	4

#### Treatment of human scabies

- Take a dose of 200 micrograms 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 Ivermectin Aristo tabletten is too strong or too weak talk to you doctor or pharmacist.

#### **Method of administration**

##### 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.
- [for 6 mg only] The tablet can be divided in equal doses.

##### 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 prescribed for you at the same time.
- The dose depends on your illness and your weight or your height.

#### **If you take more Ivermectin Aristo tabletten than you should**

Take exactly the dose of this medicine that your doctor has told you.

Some patients experienced loss of consciousness or coma after taking too much of this medicine. If you have taken too much of this medicine, contact your doctor or pharmacist immediately.

#### **If you forget to take Ivermectin Aristo tabletten**

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

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).

##### Other side effects

- asthma
- difficult walking
- eye problems such as infection, redness or unusual feelings
- stomach pain
- constipation
- sore throat
- liver disease (acute hepatitis)
- changes in some laboratory tests (increase of liver enzymes, increase of bilirubin on blood, increase of eosinophils)
- blood in urine
- sweating
- feeling unusually weak
- loss of consciousness or coma

The side effects below depend on what you are taking Ivermectin Aristo tabletten for. They also depend on whether you have any other infections.

**People with intestinal strongyloidiasis (anguillulosis)** may have the following side effect:

- feeling unusually weak
- loss of appetite, stomach pain, constipation or diarrhea
- 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
- difficult 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
- diarrhea
- 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 you eye lids
- 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 ivermectin Aristo tabletten**

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.

Do not store above 25°C.

Store in the original package in order to protect the product 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 Ivermectin Aristo tabletten contains

- The active substance is ivermectin.

*[for 3 mg only]*

One tablet contains 3 mg ivermectin.

*[for 6 mg only]*

One tablet contains 6 mg ivermectin.

- The other ingredients are:  
Cellulose microcrystalline (E 460), citric acid (E 330), butylhydroxyanisole (E 320), starch, pregelatinised, silica, colloidal anhydrous (E 551), magnesium stearate (E 470b)

### What Ivermectin Aristo tabletten looks like and contents of the pack

*[for 3 mg only]*

This medicine is presented as a white to off white colored, round shaped, biconvex tablet having a diameter of approximately 5 mm. The tablets are available in boxes containing OPA-Aluminium-PVC-blisters with 4, 6, 8 or 10 tablets.

*[for 6 mg only]*

This medicine is presented as a white to off white colored, round shaped, biconvex tablet with a breakmark having a diameter of approximately 6 mm. The tablets are available in boxes containing OPA-Aluminium-PVC-blisters with 2, 4 or 12 tablets

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

Vergunninghouder:  
Aristo Pharma GmbH  
Wallenroder Straße 8-10,  
13435 Berlin, Duitsland

Fabrikant:  
Aristo Pharma GmbH  
Wallenroder Straße 8-10,  
13435 Berlin, Duitsland

Laboratorios Medicamentos Internacionales S.A.  
Calle De La Solana 26, Torrejon De Ardoz, Madrid  
28850 Spanje

### In het register ingeschreven onder:

Ivermectine Aristo 3 mg, tabletten	RVG 133954
Ivermectine Aristo 6 mg, tabletten	RVG 133955

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

Czechia:	Ivermectin Aristo tabletten
Germany:	Ivermectin Aristo tabletten 3 mg Tabletten Ivermectin Aristo tabletten 6 mg Tabletten
Netherlands:	Ivermectine Aristo 3 mg, tabletten Ivermectine Aristo 6 mg, tabletten
Poland:	Vesarco

Spain: Ivermectina Aristo tabletten 3 mg comprimidos EFG  
Ivermectina Aristo tabletten 6 mg comprimidos EFG

**Deze bijsluiter is voor het laatst goedgekeurd in december 2025.**