Ivermectin 3mg tablet

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 3 mg tablet is and what it is used for 2. What you need to know before you take Ivermectin 3 mg tablet
- 3. How to take Ivermectin 3 mg tablet
- 4. Possible side effects
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1. WHAT Ivermectin 3mg tablet IS AND WHAT IT IS USED FOR

Pharmacotherapeutic class - ATC code: ANTHELMINTICS - P02CF01.

This medicine is an antiparasitic

Ivermectin 3 mg tablet 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:

- \bullet an infestation of the intestine called intestinal strongyloidosis (anguillulose). It is due to a type of roundworm called «*Strongyloides stercoralis*»; • an infestation of blood called microfilaraemia due to
- lymphatic filariasis. It is caused by an immature worm called «Wuchereria bancrofti». Ivermectin 3 mg tablet does not work on adult worms but only against immature worms;
- skin mites (scabies). This is when tiny mites burrow under your skin. This can cause you severe itching. Ivermectin 3 mg tablet should only be taken when your doctor is certain or thinks you have scabies.

Ivermectin 3 mg tablet will not prevent you from having one of these infestations. It is not effective on adult worms. Ivermectin 3 mg tablet should only be taken with the advice of your doctor when the parasite infestation is certain or is strongly suspected.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE roundworms can also be found in your stool. Ivermectin 3 mg tablet

Do not take Ivermectin 3mg tablet:

 if you are allergic to ivermectin or any of the other ingredients of this medicine. Symptoms of an allergic reaction to a medicine may include skin rash, difficulty breathing or fever

Do not take Ivermectin 3 mg tablet if you have any of the above symptoms. If in doubt, contact your doctor or pharmacist before taking Ivermectin 3 mg tablet.

Warning and precautions

Talk to your doctor or pharmacist before taking Ivermectin 3 mg tablet.

In particular, before taking your medicine, check with your doctor or pharmacist:

- · if you have a deficient immune system,
- 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. The use of diethylcarbamazine citrate (DEC) to treat «Onchocerca volvulus» infestation may increase the risk of adverse effects that can sometimes be serious.

If any of the above apply to you (or if you are not sure), contact your doctor or pharmacist before taking Ivermectin 3 mg tablet.

Children

The safety of using Ivermectin 3 mg tablet in children weighing less than 15 kg has not been evaluated.

Other medicines and Ivermectin 3 mg tablet

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 or may become pregnant, contact your doctor immediately before taking Ivermectin 3 mg tablet. If you are pregnant, take Ivermectin 3 mg tablet only when absolutely necessary. The decision will be made in agreement with your doctor.
- · Contact your doctor if you are breast-feeding or intend to breast-feed, as Ivermectin 3mg, tablet passes into breast decide week after the birth of your child.

Treatment of human scabies:

Take a dose of 200 micrograms of ivermectin per kilogram of body weight.

You will not know, for 4 weeks, if the treatment was totally effective. Your doctor may prescribe a second single dose within 8 to 15 days.

If you take more Ivermectin 3mg tablet than you should

If you take more Ivermectin 3 mg tablet than you should, please contact your doctor immediately.

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

If you forget to take Ivermectin 3mg tablet

Try taking Ivermectin 3 mg tablet according to your doctor's prescription. Do not take a double dose to make up for a forgotten dose.

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 occur with this medicine:

Allergic reactions

If you have an allergic reaction, see a doctor immediately. Symptoms may include:

- sudden fever,
- sudden skin reactions (such as skin rash or itching) or other serious skin reactions,
- difficulty breathing.

See a doctor straight away if you get any of the above side effects.

Other side effects

- liver disease (acute hepatitis),
- modification of some laboratory tests (increase of liver enzymes, increase of bilirubin on blood, increase of eosinophil levels)
- presence of blood in urine.

The side effects listed below depend on what you are taking Ivermectin 3 mg tablet. They also depend on the presence or absence of other infections.

People with intestinal strongyloidiasis (anguillulose) may have the following side effects:

- feeling unusually weak,
- loss of appetite, stomach pain, constipation or diarrhea,
- nausea or vomiting,
- feeling sleepy or dizzy,
- shaking or tremors.

In case of intestinal strongyloidosis (anguillulose), adult

People with microfilaraemia due to lymphatic

filariasis caused by Wuchereria bancrofti may have the following side effects:

- sweats or fever,
- headache,
- feeling unusually weak,
- muscle, joint and whole body pain,
- loss of appetite, nausea,
- stomach pain (abdominal and epigastric pain), painful cough or throat;
- difficulty breathing,
- low blood pressure when standing up you may feel dizzy or light-headed,
- chills,
- dizziness
- pain or discomfort in the 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.

Highly infested individuals with Loa loa worm may

- have the following side effects: disorders of the brain function,
- neck pain or back pain,
- bleeding in the white of the eye (also called red eye),
- shortness of breath,
- loss of control of the bladder or intestines,
- difficulty standing or walking,
- disorders of the mental state,
- · feeling drowsy or confused,
- unable to respond to other people or coma.

Infected individuals with the worm «Onchocerca volvulus» responsible for river blindness may have the following side effects

- itching or rash,
- joint or muscle pain,
- fever,
- nausea or vomiting, swelling of the lymph nodes,
- swelling, especially in the hands, ankles or feet,

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 side effects such as dizziness, drowsiness, or feeling shaky or like you are spinning after taking Ivermectin 3 mg tablets. If you experience such symptoms, avoid driving vehicles or operating machinery.

3. HOW TO TAKE Ivermectin 3 mg tablet

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 the medicine

- Take this medicine orally.
- In children less than 6 years, tablets should be crushed before swallowing.
- Take the number of tablets prescribed by your doctor at one time, with water and on an empty stomach. No food should be taken 2 hours before or after administration because the influence of diet on the absorption of the medicine by your body is not known.

Dosage

The treatment consists of a single dose.

- Take the number of tablets prescribed by your doctor at one time.
- The dose depends on your illness as well as your weight or height.
- Your doctor will tell you how many tablets to take.

Treatment of intestinal strongyloidosis (anguillulose): The usual dosage 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 due to lymphatic filariasis, caused by Wuchereria bancrofti:

The usual dose is:	
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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

The dose will be repeated every 6 months or every 12 months

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 (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	— t wo —	— fou r —
141 to 158	three	six
> 158	four	eight

- diarrhea dizziness,
- low blood pressure (hypotension). You may feel dizzy or light-headed when standing up,
- fast heart rate,
- headache or feeling tired,
- vision problems and other eve problems such as infection. redness or unusual sensations,
- bleeding in the white of the eye or swelling of the eyelids,
- 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 numbers listed at the end of this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE Ivermectin 3mg tablet

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 box and the blister. The expiry date refers to the last day of that month.

Store at a temperature not exceeding 25°C.

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 Ivermectin 3 mg tablet contains The active substance is:

vermectin

.....3 mg For one tablet.

What Ivermectin 3mg tablet looks like and other information

This medicine is in tablet form. Box of 4 tablets.

Marketing Authorisation Holder Tadbirkala Jam (tekaje)

Tehran-Iran

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Manufacturer EUROPHARTECH

France

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