Package leaflet: Information for the user

Ivermectin 3 mg tablets

This medicinal product is known by the above name but will be referred to as Ivermectin throughout this leaflet.

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 is and what it is used for
2. What you need to know before you take Ivermectin
3. How to take Ivermectin
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1. What Ivermectin is and what it is used for

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

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

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

Warnings and precautions
Talk to your doctor before taking Ivermectin.
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 Ivermectin, tell your doctor about all your medical history. Tell your doctor
- if you have a weak 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.

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 Ivermectin.

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

Other medicines and Ivermectin
Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

Ivermectin with food, drink and alcohol
Not relevant.

Pregnancy and breast-feeding
- If you are pregnant or may become pregnant, tell your doctor immediately before taking this medicine. If you are pregnant, you should only take it if it is clearly necessary. You and your doctor will decide this in consultation.
- Consult with your doctor if you are or plan to breastfeed. This is because this medicine passes into breast milk. Your doctor may decide to start treatment a week after your child is born.

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 can feel dizziness, drowsiness, or feeling shaky or like you are spinning, after the use of this medicine.
If you experience such symptoms, avoid driving or using machines.

3. How to take Ivermectin

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 under six years of age, crush the tablets before taking.
- Take the number of tablets prescribed by your doctor all at once with water on an empty stomach. Do not eat anything 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 consists of a single dose.
- Take the number of tablets your doctor has prescribed all at once.
- The dose depends on your disease and your weight or height.
- The doctor will tell you how many tablets to take.

<u>Treatment of intestinal strongyloidiasis (anguillulosis)</u>
The recommended 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

<u>Treatment of microfilaraemia caused by *Wuchereria bancrofti* (lymphatic filariasis)</u>
The recommended dosage 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

This is repeated every 6 or every 12 months.
Alternatively and in the absence of a set of weighing scales, the Ivermectin dosage 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

<u>Treatment of human scabies</u>
- The dosage is 200 micrograms for each kilogram of body weight. Your doctor will tell you how many tablets you need to take.
- 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.

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

If you take more Ivermectin than you should
Take exactly the dose of this medicine that your doctor has told you. Some patients experienced decreased consciousness or coma after taking too much of this medicine. If you have taken too much of this medicine, contact a doctor immediately.

If you forget to take Ivermectin
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:

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).

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
- decreased consciousness or coma.

The side effects below depend on what you are taking Ivermectin 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 shivers

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 the 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

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ivermectin

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.

Do not use this medicine if it becomes discoloured or shows any visible signs of deterioration. Contact your pharmacist who will tell you what to do.

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 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 Ivermectin looks like and contents of the pack
This medicine is presented as a round, white or almost white, flat chamfered tablet.
Pack size of 4 tablets.

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

Procured from within the EU and repackaged by the Product Licence holder:
Pharmaram Limited, Unit F4 Tom Bill Way, Ivanhoe Business Park, Ashby de la Zouch, Leicestershire
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POM

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