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Ivermectin/Albendazole (*ivermectin / albendazole*)

An overview of Ivermectin/Albendazole and why it received a positive opinion

What is Ivermectin/Albendazole and what is it used for?

Ivermectin/Albendazole is a medicine used in adults and children from 5 years of age to treat the following parasitic worm infections:

- soil-transmitted helminth (STH) infections caused by hookworms (*Ancylostoma duodenale, Necator americanus*), roundworms (*Ascaris lumbricoides, Strongyloides stercoralis*) and whipworms (*Trichuris trichiura*). STH infections are intestinal worm infections that spread through soil contaminated by human faeces in areas with poor sanitation;
- proven or suspected microfilaraemia (the presence of worm larvae in the blood) in patients with lymphatic filariasis (LF) caused by *Wuchereria bancrofti*. LF, commonly known as elephantiasis, is a disease that mainly impairs the lymphatic system (a network of vessels that transport fluid from tissues through the lymph nodes and into the bloodstream) and can lead to abnormal enlargement of body parts.

Ivermectin/Albendazole contains the active substances ivermectin and albendazole.

Ivermectin/Albendazole is intended for use outside the EU.

How is Ivermectin/Albendazole used?

Treatment with Ivermectin/Albendazole should be started by a healthcare professional experienced in managing helminth infections. The medicine should be used in accordance with official guidance, which may include guidance provided by the World Health Organization and public health authorities.

Ivermectin/Albendazole is available as orodispersible tablets to be placed on the tongue, where they rapidly dissolve upon contact with saliva. The recommended dose is one tablet for three consecutive days, taken with or after a meal. The dissolved tablet can also be given through a feeding tube.

For mass drug administration (MDA; when all people in an area are given treatment regardless of their disease status), the recommended dose is one tablet given as one single dose, once a year. If required, the dose may be given twice a year (every 6 months) in line with national treatment plans.

Arrangements for supply of the medicine will be the responsibility of national medicines regulators.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact Telephone +31 (0)88 781 6000 An agency of the European Union

For more information about using Ivermectin/Albendazole, see the package leaflet or contact your healthcare provider.

How does Ivermectin/Albendazole work?

The active substances in Ivermectin/Albendazole, ivermectin and albendazole, act together to kill the parasites. Ivermectin targets the parasite's nervous and muscular systems, causing paralysis, while albendazole disrupts the parasite's metabolism and energy production. Ivermectin and albendazole are already authorised on their own for treating parasitic infections. Their combination increases the effects against a wide range of parasites.

What benefits of Ivermectin/Albendazole have been shown in studies?

The benefits of Ivermectin/Albendazole were investigated in one main study involving around 1,000 young adults and children from five years of age.

Ivermectin/Albendazole was shown to be more effective than albendazole on its own in the treatment of infections caused by the whipworm *T. trichiura*: 97% of people given Ivermectin/Albendazole for three consecutive days and 83% of people given a single dose of the medicine were cured of the parasite, compared with 36% of people given a single dose of albendazole on its own. Ivermectin/Albendazole given for three consecutive days was also more effective than a single dose of albendazole alone in the treatment of hookworm infection caused by *A. duodenale* or *N. americanus*.

What are the risks associated with Ivermectin/Albendazole?

For the full list of side effects and restrictions with Ivermectin/Albendazole, see the package leaflet.

The most common side effects with Ivermectin/Albendazole (which may affect more than 1 in 10 people) include abdominal (belly) pain, headache and increased blood levels of liver enzymes (a sign of possible liver problems).

The most serious side effects for ivermectin that are known from the published literature are encephalopathy (brain disorder caused by a harmful substance or infection) in patients also heavily infected with *Loa loa* (a parasite also known as the African eye worm), toxic epidermal necrolysis and Stevens-Johnson syndrome (two life-threatening reactions with flu-like symptoms and painful rash or blistering affecting the skin, mouth, eyes and genitals); for albendazole, these are hepatotoxicity (liver damage) and myelosuppression (a condition in which the bone marrow cannot make enough blood cells).

During MDA campaigns, Ivermectin/Albendazole must not be used in women who are pregnant or who intend to become pregnant. Before starting treatment with Ivermectin/Albendazole, pregnancy should be excluded. Because albendazole may cause birth defects in the unborn baby, women who could become pregnant should use effective contraception shortly before, during, and up to one month after treatment with Ivermectin/Albendazole, both for individual treatment and for treatment during MDA campaigns.

Ivermectin/Albendazole must not be used in patients with high microfilaria caused by *L. loa* and for MDA campaigns in regions where *L. loa* is endemic, unless a feasible and validated risk mitigation strategy can be put in place; this is because the side effects of ivermectin may be more severe in people infected with *L. loa*.

Why did Ivermectin/Albendazole receive a positive opinion?

The main study showed that Ivermectin/Albendazole is effective at treating soil-transmitted helminth infections caused by *T. trichiura*, *A. duodenale* and *N. americanus.* In the study, there were too few people infected with *S. stercoralis* or *A. lumbricoides* to establish the effect of Ivermectin/Albendazole in the treatment of these infections. However, as medicines containing ivermectin or albendazole on their own are effective against these parasites, Ivermectin/Albendazole is expected to have the same effect on these infections. Similarly, as ivermectin on its own is effective at treating microfilaraemia due to *W. bancrofti,* Ivermectin/Albendazole can be used to replace ivermectin for the treatment of lymphatic filariasis caused by this parasite.

The safety of ivermectin and albendazole has been widely documented, as both have been extensively used in MDA campaigns involving a high number of people. In studies with Ivermectin/Albendazole, most side effects were mild or moderate in intensity and resolved without medical intervention.

In addition, Ivermectin/Albendazole is considered a convenient alternative to the administration of ivermectin and albendazole on their own; the availability of orodispersible tablets is also considered a major advantage over regular tablets, possibly reducing the number of choking episodes in young children during MDA campaigns.

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) therefore concluded that the benefits of the medicine outweigh its risks and issued a positive scientific opinion.

What measures are being taken to ensure the safe and effective use of Ivermectin/Albendazole?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Ivermectin/Albendazole have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Ivermectin/Albendazole are continuously monitored. Suspected side effects reported with Ivermectin/Albendazole are carefully evaluated and any necessary action taken to protect patients.

Other information about Ivermectin/Albendazole

The European Medicines Agency gave a positive opinion for Ivermectin/Albendazole on 30 January 2025.

The Agency assessed Ivermectin/Albendazole as part of its cooperation with the World Health Organization, whereby the Agency evaluates medicines that are not intended for use in the EU but are needed to prevent or treat diseases of major public health importance around the world.

Further information on Ivermectin/Albendazole can be found on the Agency's website: www.ema.europa.eu/medicines/human/EPAR/ivermectin-albendazole

This overview was last updated in 03-2025.