30 January 2025
EMA/CHMP/28710/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion

Ivermectin/Albendazole

ivermectin / albendazole

On 30 January 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion in accordance with Article 58 of Regulation (EC) No 726/2004[1] for the medicinal product Ivermectin/Albendazole, intended for the treatment of soil-transmitted helminth infections and microfilaraemia in patients with lymphatic filariasis.

This medicinal product has been developed by Laboratorios Liconsa, S.A.

Ivermectin/Albendazole is a fixed dose combination of ivermectin and albendazole, and will be available as orodispersible tablets containing either 9 mg ivermectin and 400 mg albendazole, or 18 mg ivermectin and 400 mg albendazole. The active substances of Ivermectin/Albendazole are ivermectin and albendazole, anthelmintics, antinematodal agents (ATC code: not yet assigned). When co-administered, ivermectin and albendazole act synergistically to enhance parasite clearance. Ivermectin targets the parasite's nervous and muscular systems, causing paralysis, while albendazole disrupts the parasite´s metabolism and energy production. This dual approach immobilises and kills the parasite through complementary pathways, improving the treatment´s effectiveness against several helminths.

The main study demonstrated that Ivermectin/Albendazole, given as a single dose in one day or as a single dose on 3 consecutive days, was significantly more effective than albendazole alone in curing *T. trichiura* infections. The fixed-dose combination, given as a single dose on 3 consecutive days, was also more effective than albendazole alone in curing hookworm infection. The most common side effects with Ivermectin/Albendazole are headache, abdominal pain and elevated liver enzymes.

The full indication is:

> Ivermectin/Albendazole orodispersible tablets are indicated in adults, adolescents and children ≥ 5 years of age for the treatment of:
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> - Soil-transmitted helminth infections, caused by one or more of the following parasites (see section 5.1): Hookworm (*Ancylostoma duodenale, Necator americanus*), Roundworm (*Ascaris lumbricoides*), Whipworm (*Trichuris trichiura*) and *Strongyloides stercoralis*.

[1] Scientific opinion in accordance with Article 58 of (EC) No Regulation 726/2004 in the context of cooperation with the World Health Organisation (WHO)

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- Proven or suspected microfilaraemia in patients with lymphatic filariasis caused by *Wuchereria bancrofti*.

Ivermectin/Albendazole should be used in accordance with official guidance, which may include guidance provided by the World Health Organisation and public health authorities.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR).

Ivermectin/Albendazole is intended exclusively for markets outside the European Union.