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New recommendations for oral suspension veterinary medicines containing albendazole for sheep

On 16 April 2026, the EMA's veterinary medicines committee, CVMP, completed a review concluding that the benefits of oral suspension veterinary medicines containing albendazole for sheep continue to outweigh their risks, provided some changes are made to their product information. Particularly, changes to the dosage regimen (dose rate and duration of treatment) for concerned veterinary medicines indicated for the treatment of gastrointestinal nematodes in sheep. The Committee also recommended to add appropriate warnings as a complementary risk management measure to further mitigate the emergence and spread of resistant parasite populations.

Oral solution veterinary medicines containing albendazole are marketed in many European Union Member States and have been widely used for decades in cattle, sheep, goats, pigs, rabbits, birds, dogs and cats. In ruminants, and in particular in sheep, they are used for the treatment of gastrointestinal nematodes, lungworms, tapeworms and adult liver flukes. However, emerging resistance has been reported throughout Europe for gastrointestinal nematodes in sheep.

The review of the CVMP was limited to the use in sheep for the treatment of gastrointestinal nematodes, specifically veterinary medicines authorised at doses or lower dose limits of 3.75-5 mg albendazole per kg bodyweight. The recommendations addressed concerns that this dosage regimen might not be appropriate to ensure effective use of these veterinary medicines, potentially contributing to the development of antiparasitic resistance.

The recommendations follow a review by the CVMP of all available data for oral solution veterinary medicines containing albendazole, including scientific literature and studies (dose determination and dose confirmation, residue depletion, target animal safety and environmental safety studies).

To ensure an effective use whilst minimising the risk of developing antiparasitic resistance to albendazole, the Committee concluded that the dose rate for the concerned veterinary medicines should be increased to 7.5 mg of albendazole per kg bodyweight administered as a single treatment for the treatment of gastrointestinal nematodes in sheep. This adjustment optimises efficacy without compromising safety, and it aligns with best parasitological practices for delaying the development of antiparasitic resistance.

The Committee also concluded that this change does not raise new safety concerns for treated animals, users, consumers or the environment. This conclusion is further supported by the fact that a

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dose of 7.5 mg of albendazole per kg bodyweight is already authorised in all concerned veterinary medicines for another indication in sheep.

The CVMP considered it beneficial to include warnings in the product information to state additional strategies, including the prevention of underdosing, maintenance of refugia, targeted selective treatment, and routine parasitological monitoring. These measures are essential to slow the emergence and spread of resistant parasite populations.

The CVMP recommendations were sent to the European Commission, which issued a final legally binding decision applicable in all EU Member States on 10 July 2026.

Information for veterinarians

- EMA recommended changes to the product information of oral solution veterinary medicines containing albendazole, to ensure that advice regarding their administration (dose rate and duration of treatment) is consistent across the EU while guaranteeing their correct use.
- Since the recommended dose for the treatment of gastrointestinal nematodes in sheep is already authorised for a different indication in all the concerned veterinary medicines, no additional concerns are expected for target animals, users, consumers or the environment.
- Appropriate warnings in the product information are recommended as a complementary risk management measure to further mitigate the emergence and spread of resistant parasite populations.

More about the medicine

Albendazole is a well-established, broad-spectrum antiparasitic medicine. Oral solution veterinary medicines containing albendazole within the scope of this referral have been used for decades in sheep to effectively treat a wide range of intestinal parasitic infections, including gastrointestinal infections with roundworms, lungworms, tapeworms and treatment of adult liver flukes.

More about the procedure

The review of oral solution veterinary medicines containing albendazole was initiated on 11 June 2025 at the request of Germany under Article 82 of Regulation (EU) 2019/6.

The review was carried out by the Committee for Veterinary Medicinal Products (CVMP), the Committee responsible for the evaluation of veterinary medicines, which made a set of recommendations. The CVMP recommendations were sent to the European Commission, which issued an EU-wide legally binding decision on 10 July 2026.