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EPAR summary for the public

Trifexis

Spinosad / milbemycin oxime

This document is a summary of the European Public Assessment Report. Its purpose is to explain how the assessment done by the Committee for Medicinal Products for Veterinary Use (CVMP) on the basis of the documentation provided, led to the recommendations on the conditions of use.

This document cannot replace a face-to-face discussion with your veterinarian. If you need more information about your animal's medical condition or treatment, contact your veterinarian. If you want more information on the basis of the CVMP recommendations, read the scientific discussion (also part of the EPAR).

What is Trifexis and what is it used for?

Trifexis is a veterinary medicine used to treat and prevent flea infestations in dogs. Trifexis is only to be used when there is also a need for one or more of the following:

- to prevent heartworm disease (roundworms that infect the heart and blood vessels and are transmitted by mosquitoes)
- to prevent lungworm disease (transmitted by eating slugs or snails)
- to treat gut infections by other types of worms (the nematodes hookworm, roundworm and whipworm).

Trifexis may also be used as part of a treatment strategy for the control of flea allergy dermatitis (an allergic reaction to flea bites).

Trifexis contains two active substances, spinosad and milbemycin oxime.

How is Trifexis used?

Trifexis should be given with food or immediately after feeding; the dose (the number of tablets of particular strengths to use) depends on the bodyweight of the dog. For the appropriate strength of tablet and number of tablets to be given, see the dosage table in the package leaflet.

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In areas where heartworm infection is known to occur, treatment should be given at monthly intervals, starting one month before the time of year when mosquitoes and fleas are present until at least one month after the last exposure to mosquitoes. Trifexis should not be given for more than six consecutive months in any one year.

In areas where heartworm infection does not occur, dogs may be given a single dose of Trifexis to prevent seasonal fleas when infections with gut worms have been diagnosed. Subsequent flea prevention should be with a different product containing a single active substance.

In areas where lungworm infection is known to occur, Trifexis should be given at monthly intervals during the time of year when snails/slugs and fleas are present until at least one month after last exposure to slugs and snails. Trifexis should not be given for more than six consecutive months in any one year.

How does Trifexis work?

One of the active substances in Trifexis, spinosad, interferes with receptors in the fleas' nervous system (nicotinic acetylcholine receptors), resulting in subsequent paralysis and death of the fleas.

The second active substance, milbemycin oxime, causes paralysis and death of worms by interfering with the way signals are passed between nerve cells in the parasites' nervous system.

Trifexis can prevent flea infestation for up to four weeks after a single administration because it kills adult fleas and reduces egg production.

What benefits of Trifexis have been shown in studies?

For prevention and treatment of flea infestations, a field study was conducted in which 178 dogs were treated with Trifexis and 88 dogs were treated with another flea medicine containing selamectin. The study showed a 90% reduction in flea count in 97% and 89% of Trifexis-treated dogs at days 14 and 30 respectively, compared with 86% and 73% in the selamectin-treated dogs.

For treatment of gut worm infections the company submitted data from a field study involving a total of 229 dogs. Trifexis-treated dogs were compared to dogs treated with milbemycin oxime alone. The measure of effectiveness was based on the proportion of dogs with at least a 90% reduction in the number of worm eggs in their faeces. The study showed the success rate with Trifexis against gut worms to be comparable to the success rate with milbemycin oxime alone.

For prevention of heartworm disease in three laboratory studies, dogs aged 4 to 9 months were artificially infected with European strains of heartworm and then treated with Trifexis at different times after infection. Treatment with Trifexis was compared with a dummy treatment containing no active substance. The studies showed that a single treatment 30 days after infection gave 100% prevention for one strain, but three consecutive monthly treatments were needed for the other less susceptible heartworm strains.

For prevention of lungworm disease, two laboratory studies were conducted in dogs which were artificially infected with European strains of lungworm and then treated with Trifexis 30 days later. The studies showed that a single treatment 30 days after infection gave 95% protection.

What are the risks associated with Trifexis?

Trifexis must not be used in puppies less than 14 weeks of age.

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Vomiting in the first 48 hours after treatment is common (seen in up to 1 in 10 animals). In most cases it is mild and short lived without requiring treatment. Other common side effects include lethargy (sluggishness), decreased appetite, diarrhoea, pruritus (itching), dermatitis (inflammation of the skin) and reddening of the skin and ear.

For a full list of all side effects reported with Trifexis, see the package leaflet.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

Accidental ingestion may cause side effects.

If the medicine is accidentally ingested, medical advice should be sought immediately and the package leaflet or label shown to the doctor.

Hands should be washed after handling the product.

Children must not come into contact with Trifexis.

Why is Trifexis approved?

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that Trifexis' benefits are greater than its risks and recommended that it be approved for use in the EU.

Other information about Trifexis:

The European Commission granted a marketing authorisation valid throughout the EU, for Trifexis on 19/09/2013.

The full EPAR for Trifexis can be found on the Agency's website: ema.europa.eu/Find medicine/Veterinary medicines/European public assessment reports. For more information about treatment with Trifexis, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in November 2016.

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