



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Veterinary Use

Summary of opinion¹

CERTIFECT

Fipronil, (S)-methoprene, Amitraz

On 9 March 2011, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,² recommending the granting of a marketing authorisation for the veterinary medicinal product CERTIFECT, a combination product containing fipronil, (S)-methoprene and amitraz. This spot-on solution is intended to be used against infestations with ticks, alone or in association with fleas and/or chewing lice.

The applicant for this veterinary medicinal product is Merial SAS.

The active substances of CERTIFECT are fipronil, (S)-methoprene and amitraz, ectoparasiticides for topical use (ATCvet code: QP53AX65) with insecticidal and acaricidal effects.

The benefits of CERTIFECT are to eliminate ticks within 24 hours, disrupt tick attachment and indirectly reduce the risk of transmission of tick-borne diseases, eliminate fleas and prevent environmental flea contamination. The most common side effects are hypersalivation, vomiting, lethargy, hyperglycaemia, bradycardia or bradypnea. Signs are transitory and generally resolve without treatment within 24 hours.

The approved indication is: "Treatment and prevention of infestations in dogs by ticks (*Ixodes ricinus*, *Dermacentor reticulatus*, *Rhipicephalus sanguineus*, *Ixodes scapularis*, *Dermacentor variabilis*, *Haemaphysalis elliptica*, *Haemaphysalis longicornis*, *Amblyomma americanum* and *Amblyomma maculatum*) and fleas (*Ctenocephalides felis* and *Ctenocephalides canis*). Treatment of infestations by chewing lice (*Trichodectes canis*). Prevention of environmental flea contamination by inhibiting the development of all flea immature stages. The product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD). Elimination of fleas and ticks within 24 hours. One treatment prevents further infestations for 5 weeks by ticks and for up to 5 weeks by fleas.

The treatment indirectly reduces the risk of transmission of tick-borne diseases (canine babesiosis, monocytic ehrlichiosis, granulocytic anaplasmosis and borreliosis) from infected ticks for 4 weeks."

¹ Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the opinion.

² Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.



Detailed conditions for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for CERTIFECT and therefore recommends the granting of the marketing authorisation.

Medicinal product no longer authorised