14 March 2025
EMA/CVMP/83482/2025
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Prazivetin

International non-proprietary name (INN): Praziquantel

On 13 March 2025, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product 'Prazivetin premix for medicated feeding stuff' intended for sea bream. The applicant for this veterinary medicinal product is Vethellas S.A. The applicant is registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

Prazivetin is an anthelmintic medicinal product containing praziquantel (ATCvet code QP52AA01) as active substance, whose mode of action is most likely based on the induction of Ca^{2+} influx-mediated muscular paralysis as well as tegumental disruption in adult worms.

The main benefit of Prazivetin is its efficacy against infestations of the gills caused by the monogenean *Sparicotyle chrysophrii*.

Prazivetin is generally well tolerated at the recommended dose, adverse reactions (temporary reduction in feed intake and increased ALT/SGPT activity indicating possible liver toxicity) are only seen at overdoses.

The full indication is: "For the treatment of ectoparasitic infestations of the gills caused by the monogenean *Sparicotyle chrysophrii*".

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC), which will be published in the Union Product Database (UPD) 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-risk balance for Prazivetin and therefore recommends the granting of the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision.
[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.

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