17 January 2014
EMA/CVMP/715528/2013
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Fungitraxx

International non-proprietary name (INN): Itraconazole

On 15 January 2014, 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 Fungitraxx 10 mg/ml oral solution for ornamental birds, intended for the treatment of aspergillosis and candidiasis in certain specified orders of ornamental birds.

The applicant for this veterinary medicinal product is Avimedical B.V., registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC. The CVMP guidelines on "minor use minor species (MUMS)" data requirements have been applied when assessing this application.

The active substance of Fungitraxx is itraconazole, a triazole antimycotic, which inhibits the synthesis of ergosterol. Itraconazole also affects membrane-bound enzyme function and membrane permeability, and as this effect is irreversible it results in structural degeneration of the fungus.

The benefits of Fungitraxx are its efficacy in the treatment of aspergillosis and candidiasis in the target species. The most common side effects in treated birds are emesis, anorexia and weight loss, however, these effects are usually mild and dose related. Fungitraxx is not authorised for use in birds intended for human consumption.

The approved indications are:

- Treatment of aspergillosis in Psittaciformes, Falconiformes, Accipitriformes, Strigiformes, and Anseriformes.
- Treatment of candidiasis in Psittaciformes.

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

[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.

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favourable benefit to risk balance for Fungitraxx and therefore recommends the granting of the marketing authorisation.