6 December 2024
EMA/CVMP/543175/2024
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Tolfenamic acid VMD

International non-proprietary name (INN): Tolfenamic acid

On 5 December 2024, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Tolfenamic acid VMD, solution for injection, intended for dogs, cats, cattle and pigs. The applicant for this veterinary medicinal product is VMD N.V.

Tolfenamic acid VMD is a medicinal product containing tolfenamic acid (ATCvet code QM01AG02) as active substance, a non-steroidal anti-inflammatory drug (NSAID) belonging to the fenamate group, which inhibits cyclo-oxygenase leading to a reduction of the synthesis of prostaglandins and thromboxanes, which are important inflammatory mediators.

Tolfenamic acid VMD is a generic of Tolfine for cattle and pigs and Tolfedine 4% solution injectable for dogs and cats. Tolfine has been authorised in the Ireland since 4 February 2000 and Tolfedine in France since 26 December 1986. Studies have demonstrated the satisfactory quality of Tolfenamic acid VMD and its bioequivalence to the reference products.

The full indication is:

Cattle:
As an adjunct in the treatment of pneumonia by improving general conditions and nasal discharge and as an adjunct in the treatment of acute mastitis.

Pigs:
As an adjunct in the treatment of Metritis Mastitis Agalactia syndrome.

Dogs:
Symptomatic treatment of inflammatory and painful conditions of the osteoarticular and musculoskeletal systems.
Reduction of post-surgical pain.

[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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Cats:
Treatment of febrile syndromes

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 Tolfenamic acid VMD and therefore recommends the granting of the marketing authorisation.