10 July 2015
EMA/CVMP/389241/2015
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Novaquin

International non-proprietary name (INN): meloxicam

On 9 July 2015, 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 Novaquin oral suspension intended for the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders in horses. The applicant for this veterinary medicinal product is Le Vet Beheer B.V. The applicant is registered as a small-and-medium sized enterprise pursuant to the definition set out in Commission Recommendation 2003/361/EC.

Novaquin is a non-steroidal anti-inflammatory drug (NSAID) medicinal product containing meloxicam (ATCvet code QM01AC06) as active substance, which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects.

The benefits of Novaquin are its efficacy in the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders in horses.

The most common side effects are those typically associated with NSAIDs (i.e. reversible urticaria and diarrhoea).

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-risk balance for Novaquin and therefore recommends the granting of the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 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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