16 February 2024
EMA/CVMP/49162/2024
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Lexylan

International non-proprietary name (INN): cefalexin

On 13-14 February 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 Lexylan, Suspension for injection, intended for cats, cattle and dogs. The applicant for this veterinary medicinal product is Emdoka. The applicant is registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

Lexylan is a cephalosporin antibiotic containing cefalexin (ATCvet code QJ01DB01) as active substance.

Cefalexin is a cephalosporin of the first generation and belongs to the beta-lactam antibiotics.

The bactericidal effect of cefalexin is based on interference with the cell membrane synthesis by inactivation of transpeptidase.

Cefalexin is mainly active against Gram-positive organisms:

- *Staphylococcus* spp. (penicillin-resistant strains included),
- *Streptococcus* spp.
- *Trueperella pyogenes*

The following Gram-negative organisms are moderately sensitive:

- *Pasteurella* spp.
- *Escherichia coli*
- *Fusobacterium* spp.

Pseudomonas spp., *Enterobacter* spp. and other *Proteus* are resistant.

Lexylan is a generic of Ceporex, which has been authorised in the EU since 21 June 1988. Studies have demonstrated the satisfactory quality of Lexylan, and its bioequivalence to the reference product Ceporex.

[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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The full indication is:

This veterinary medicinal product is indicated for the treatment of diseases caused by cefalexin susceptible micro-organisms at well accessible infection sites, within the limits of effective cefalexin concentrations.
Cattle:
Metritis, interdigital dermatitis, wounds and abscesses, treatment of septicemic mastitis in addition of an intramammary therapy.
Dogs:
Infections of the respiratory tract, the uro-genital system, the skin, soft tissues and the gastro-intestinal system.
Cats:
Infections of the respiratory tract, the uro-genital system, the skin and soft tissues.

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 Lexylan and therefore recommends the granting of the marketing authorisation.