**IPAR**

**Publicly Available Assessment Report for a**
**Veterinary Medicinal Product**

Noroclav Injection for Cattle, Dogs and Cats

**PRODUCT SUMMARY**

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| EU Procedure number | IE/V/0585/001 |
| Name, strength and pharmaceutical form | Noroclav Injection for Cattle, Dogs and Cats.<br>Suspension for injection containing 140 mg/ml of amoxicillin (as amoxicillin trihydrate) and 35 mg/ml clavulanic acid (as potassium clavulanate). |
| Active substance(s) | Amoxicillin trihydrate, potassium clavulanate |
| Marketing Authorisation Holder | Norbrook Laboratories (Ireland) Limited<br>Rossmore Industrial Estate<br>Monaghan<br>Ireland |
| Legal basis of application | Article 13 of Directive 2001/82/EC, as amended (generic application). |
| Date of completion of the original authorisation procedure | 21/11/2001 |
| Date first authorised in the RMS | 27/09/2002 |
| Target species | Cattle, dogs and cats |
| Indication(s) for use | The veterinary medicinal product has a broad-spectrum of bactericidal activity against the bacteria commonly found in cattle, dogs and cats.<br><br>*a) In vitro* the veterinary medicinal product is active against a wide range of clinically important bacteria including:<br><br>Gram-positive: Staphylococci (including beta-lactamase producing strains), Streptococci, Corynebacteria, Clostridia, *Bacillus anthracis*, *Actinomyces bovis*.<br>Gram-negative: *Escherichia coli* (including beta-lactamase producing strains), *Salmonella* spp. (including beta-lactamase producing strains), *Campylobacter* spp., *Klebsiella* spp., *Proteus* spp., *Pasteurellae* spp., *Fusobacterium necrophorum*, Bacteroides (including beta-lactamase producing strains), *Haemophilus* spp., *Moraxella* spp. and *Actinobacillus lignieresi*.<br>*b)* The veterinary medicinal product is indicated for the treatment of diseases including:<br><br><u>Cattle:</u><br>Respiratory infections<br>Soft tissue infections (e.g. joint/navel ill, abscesses etc.)<br>Metritis<br>Mastitis<br><br><u>Dogs and cats:</u><br>Respiratory tract infections<br>Urinary tract infections<br>Skin and soft tissue infections (e.g. abscesses, pyoderma, anal sacculitis and gingivitis.) |
| ATCvet code | QJ01CR02 |
| Concerned Member States | UK (NI) |

**PUBLIC ASSESSMENT REPORT**

The public assessment report reflects the scientific conclusion reached by the Health Products Regulatory Authority (HPRA) at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the

specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in relevant articles of Regulation (EU) 2019/6. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this product are available in the Union Product Database (UPD).

## I. SCIENTIFIC OVERVIEW

The initial application for the product was assessed in 2001, before there was a requirement to have a public assessment report, therefore no details in this section are available.
Please refer to Section VI of this PuAR document for significant post-approval changes which are important for the quality, safety and efficacy of the product.

## II. QUALITY ASPECTS

See Section I.

## III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

See Section I.

## III. SAFETY ASSESSMENT

See Section I.

## IV. CLINICAL ASSESSMENT

See Section I.

## V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

On the basis of the original data submitted, it was agreed that the product demonstrated adequate evidence of efficacy for the approved indications as well as a satisfactory benefit/risk profile and therefore was granted a marketing authorisation.

## VI. POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Union Product Database. This section contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

**Changes to Part 3 and/or Part 4 of the dossier (safety/efficacy)**

| Summary of change (Application number) | Supporting information | Approval date |
|---|---|---|
| Addition of target species - cats IE/V/0585/001/A/028 | Bioequivalence with the reference product Synulox Ready to Use Suspension for Injection (IE: VPA 10387/075/001; UK: Vm 60021/3021) | 26/02/2026 |

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| | was accepted based on fulfilment of the criteria for a biowaiver under Section 7.1 d) of the CVMP Guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/EWP/16/2000-Rev.4).<br>As bioequivalence with the reference product was demonstrated, omission of proprietary data supporting safety and efficacy of the VMP in the target species cats was considered acceptable. Further bibliographic data relating to certain aspects of the safety and efficacy of the veterinary medicinal product in the target species cats, and information concerning development of antimicrobial resistance were also provided.<br><br>Qualified for data protection: no | |