1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norocillin 300 mg/ml Suspension for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Procaine Benzylpenicillin 300 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Hydroxybenzoate esters - Containing Ethyl Parahydroxybenzoate (E214), Propyl Parahydroxybenzoate (E216), Methyl Parahydroxybenzoate (E218)	1.5 mg
Povidone K12	
Disodium Edetate Dihydrate	
Potassium Dihydrogen Phosphate	
Sodium Citrate Dihydrate	
Polysorbate 80	
Lecithin	
Simeticone	
Water for Injections	

A white/off-white suspension

3. CLINICAL INFORMATION

3.1 Target species

Horses, Cows, Sheep, Pigs.

3.2 Indications for use for each target species

For the treatment of systemic infections caused by or associated with organisms sensitive to penicillin. *In vitro* tests have shown the following organisms to be sensitive:

Trueperella pyogenes
Erysipelothrix rhusiopathiae
Listeria spp.
Mannheimia haemolytica
Pasteurella multocida
Staphylococcus spp. (non penicillinase producing)
Streptococcus spp.

The veterinary medicinal product will therefore be effective in the treatment of infections caused by susceptible organisms including:

Erysipelas; navel/joint ill; respiratory tract infections including pneumonia and atrophic rhinitis; listeriosis; meningitis; septicaemia; toxaemia associated with mastitis; urogenital tract infections and the control of secondary bacterial invaders in diseases of primary viral origin.

3.3 Contraindications

Do not inject intravenously.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in sheep producing milk for human consumption.

3.4 Special warnings

After absorption, benzylpenicillin poorly penetrates biological membranes (e.g., blood-brain barrier) since it is ionised and poorly lipid soluble. Use of the product for treatment of meningitis or CNS infections due to e.g., *Streptococcus suis* or *Listeria monocytogenes* may not be efficacious. Furthermore, benzylpenicillin penetrates mammalian cells poorly and hence this product may have little effect in treating intracellular pathogens e.g., *Listeria monocytogenes*.

Elevated MIC values or bi-modal distribution profiles suggesting acquired resistance have been reported for the following bacteria:
- *Glaesserella parasuis*, *Staphylococcus* spp. causing MMA/PPDS, *Streptococcus* spp. and *S. suis* in pigs;
- *Fusobacterium necrophorum* causing metritis and *Mannheimia haemolytica*, as well as *Bacteroides* spp., *Staphylococcus chromogenes*, *Actinobacillus lignieresii* and *Trueperella pyogenes* in cattle.

Use of the veterinary medicinal product may result in a lack of clinical efficacy when treating infections caused by these bacteria.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Administer by deep injection only.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Penicillin and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross sensitivity to cephalosporins and vice versa. Allergic reaction to these substances may occasionally be serious.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.

2. Handle this product with care to avoid exposure, taking all recommended precautions.

3. If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and may require urgent medical attention.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Target species: Cows, Sheep.
No adverse reactions.

Target species: Horses.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Death

Target species: Pigs.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting[1]; Pyrexia[1, 3], Listless[1]; Shivering[1], Incoordination[1]; Vaginal discharge[2]

[1] In suckling and fattening pigs.
[2] In pregnant sows and gilts, which could be associated with abortion.
[3] Transient.

Systemic toxic effects have been observed in young piglets, which are transient but can be potentially lethal, especially at higher doses.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
The veterinary medicinal product can be safely administered to pregnant and lactating animals.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Administer by intramuscular route after shaking to ensure re-suspension. Normal aseptic precautions should be observed. The recommended dosage rate is 10 mg/kg bodyweight procaine penicillin, equivalent to 1 ml per 30 kg bodyweight daily in cattle, sheep and pigs; and 12 mg/kg bodyweight in horses.

The treatment duration is 3 to 7 days.

The appropriate treatment duration should be chosen based on the clinical needs and individual recovery of the treated animal. Consideration should be given to the accessibility of the target tissue and characteristics of the target pathogen.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Milk for human consumption must not be taken during treatment.

Animals must not be slaughtered for human consumption during treatment.

Cattle:
Meat and offal: 5 days for treatment duration 3 -5 days.
7 days for treatment duration 6 -7 days.
Milk: 96 hours.

Sheep:
Meat and offal: 5 days for treatment duration 3 -5 days.
7 days for treatment duration 6 -7 days.
Not authorised for use in ewes producing milk for human consumption.

Pigs:
Meat and offal: 5 days for treatment duration 3 -5 days.
7 days for treatment duration 6 -7 days.

Horses:
Meat and offal: 28 days for treatment duration 3 – 5 days.
30 days for treatment duration 6 – 7 days.
Not authorised for use in mares producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATC Vet Code:

QJ01CE09

4.2 Pharmacodynamics

The veterinary medicinal product is administered by deep intramuscular injection to create a depot from which benzylpenicillin is slowly liberated. It exerts its effect on multiplying bacteria by interfering with the formation of the cell wall.

Enterobacterales, *Bacteroides fragilis*, most *Campylobacter* spp., *Nocardia* spp. and *Pseudomonas spp*. as well as beta-lactamase–producing *Staphylococcus* spp. are resistant.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 24 months
Shelf life after first opening the immediate packaging: 28 days

5.3 Special precautions for storage

Store in a refrigerator (2ºC – 8ºC).
Protect from light.

5.4 Nature and composition of immediate packaging

50 ml and 100 ml multidose type II clear glass vials closed with bromobutyl rubber bungs and aluminium caps.
50 ml, 100 ml and 250 ml multidose clear polyethylene terephthalate (PET) vials closed with bromobutyl rubber bungs and aluminium caps.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22664/012/001

8. DATE OF FIRST AUTHORISATION

01/10/1987

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

07/06/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).