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:

*Hydroxybenzoate esters	1.5 mg

(*containing Ethyl Parahydroxybenzoate (E214), Propyl Parahydroxybenzoate (E216), Methyl Parahydroxybenzoate (E218)

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection.
White/off-white suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Horses, Cows, Sheep, Pigs.

4.2 Indications for use, specifying the 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.

4.3 Contraindications

Do not inject intravenously.
Do not use in known cases of hypersensitivity to penicillins.
Do not use in sheep producing milk for human consumption.

4.4 Special Warnings for each target species

Occasionally in suckling and fattening pigs, administration of Norocillin may cause a transient pyrexia, vomiting, shivering, listlessness and inco-ordination.

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 c*hromogenes, *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.

4.5 Special precautions for use

Special precaution(s) for use in animals

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 doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and may require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

Occasional, potentially fatal reactions associated with the administration of procaine penicillin in horses have been observed.

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

4.7 Use during pregnancy, lactation or lay

Norocillin can be safely administered to pregnant and lactating animals. However in pregnant sows and gilts a vulval discharge which could be associated with abortion has been reported.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Not applicable.

4.11 Withdrawal period

Milk for human consumption must not be taken during treatment.
Milk for human consumption may only be taken from cows after 96 hours after the last treatment.
Animals must not be slaughtered for human consumption during treatment.

Cattle, sheep and 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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial

ATC Vet Code: QJ01CE09

5.1 Pharmacodynamic properties

Procaine Penicillin 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate (E218)
Ethyl Parahydroxybenzoate (E214)
Propyl Parahydroxybenzoate (E216)
Povidone K12
Disodium Edetate Dihydrate
Potassium Dihydrogen Phosphate
Sodium Citrate Dihydrate
Polysorbate 80
Lecithin
Simeticone
Water for Injections

6.2 Incompatibilities

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

6.3 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

6.4 Special precautions for storage

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

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8. MARKETING AUTHORISATION NUMBER(S)

VPA22664/012/001

9. DATE OF FIRST AUTHORISATION

1st October 1987

10. DATE OF REVISION OF THE TEXT

24 April 2024