SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norocillin 30% w/v Suspension for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
Procaine Penicillin 300 mg/ml (30.0% w/v)

Excipients:

Methyl Parahydroxybenzoate	0.112% w/v
Ethyl Parahydroxybenzoate	0.023% w/v
Propyl Parahydroxybenzoate	0.016% w/v

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for Injection
A white to off-white suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle
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, Mannheima haemolytica, Pasteurella multocida, Staphylococcus* spp (non-penicillinase producing) and *Streptococcus* spp.

Norocillin is recommended, therefore, in the treatment of diseases caused by susceptible organisms including:
erysipelas; navel/joint-ill; respiratory tract infections including pneumonia and atrophic rhinitis; listeriosis; septicaemia; urogenital tract infections and the control of secondary bacterial invaders in diseases of primary viral origin.

4.3 Contraindications

Do not inject intravenously or intrathecally.
Do not use in known cases of hypersensitivity to penicillin.
Not to be used on very small herbivores such as guinea pigs, gerbils and hamsters.

4.4 Special Warnings for each target species

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.

4.5 Special precautions for use

(i) Special precautions for use in animals
Shake the container before use.
Care should be taken not to overdose.
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local epidemiological information.

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

Care should be taken to avoid accidental self-injection.
Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and vice versa. Allergic reactions 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 great 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 require urgent medical attention.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Very rarely, in sucking and fattening pigs, administration may cause a transient pyrexia, vomiting, shivering, listlessness and in-coordination.

In very rare cases hypersensitivity reactions may occur. Such reactions may evolve to a more severe condition (anaphylaxis), which may be life-threatening. Potentially fatal reactions associated with the administration of procaine penicillin in horses have been observed.

The frequency of adverse reactions is defined using the following convention:
very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
common (more than 1 but less than 10 animals in 100 animals)
uncommon (more than 1 but less than 10 animals in 1,000 animals)
rare (more than 1 but less than 10 animals in 10,000 animals)
very rare (less than 1 animal in 10,000 animals, including isolated reports).

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 deep intramuscular injection only.
The recommended dose rate is: 10 mg/kg bodyweight (1ml/30 kg) daily for 3 to 7 days.
To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

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

Penicillins show a wide margin of safety.

4.11 Withdrawal period

Cattle: Milk – 84 Hours.
Cattle, sheep and pigs
Meat and offal: 7 days for treatment duration 3-5 days
9 days for treatment duration 6-7 days

Do not use in sheep producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use.

ATC Vet Code: QJ01CE09

5.1 Pharmacodynamic properties

Antimicrobial activity is achieved by interference in the final stage of bacterial cell wall synthesis by binding to the PBP's (penicillin binding proteins).

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
Ethyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Povidone K12
Disodium Edetate Dihydrate
Potassium Dihydrogen Phosphate
Sodium Citrate Dihydrate
Polysorbate 80
Simeticone
Water for Injections

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:
2 years
Shelf life after first opening the immediate packaging: 28 Days

6.4 Special precautions for storage

Following withdrawal of the first dose, use the product within 28 days.
Discard unused material.
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, 250 ml and 500 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 product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4099

9. DATE OF FIRST AUTHORISATION

20 April 1998

10. DATE OF REVISION OF THE TEXT

June 2024

Approved 18 June 2024
Gavin Hall