

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norocillin Veterinary

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Procaine Benzylpenicillin 300 mg/ml

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

Norocillin is recommended in the treatment of diseases caused by susceptible organisms to penicillin in cattle, sheep and pigs.

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.

- Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form:

<https://sideeffects.health.gov.il>

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 5 days.

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

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

Penicillins show a wide margin of safety.

4.11 Withdrawal period

Cattle:	Meat – 7 Days. Milk – 72 Hours.
Pigs:	Meat – 7 Days.
Sheep:	Meat – 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

Nipasept composed of:
Methyl Parahydroxybenzoate
Ethyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Povidone K12
Disodium Edetate Dihydrate
Potassium Acid Phosphate
Sodium Citrate Dihydrate
Polysorbate 80
Antifoam M30
Potassium Chloride
Water for Injections

6.2 Incompatibilities

None known.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.
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 (2°C – 8°C). Protect from light.

6.5 Nature and composition of immediate packaging

50 ml, 100 ml and 500 ml multidose type II clear glass 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. MANUFACTURER

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8. IMPORTER AND MARKETING AUTHORISATION HOLDER

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9. MARKETING AUTHORISATION NUMBER

083-40-92360-00

10. DATE OF REVISION OF THE TEXT

Revised in July 2025 according to MoH's guidelines.