

1. NAME, FORM AND STRENGTH OF THE VETERINARY MEDICINE

Norocillin Veterinary, suspension for injection 300 mg/ml

2. ACTIVE INGREDIENT:

Each 1 ml of the medicinal product contains:

Procaine Benzylpenicillin 300 mg

The medicine also contains preservatives:

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 13 "Further information".

3. Indications for use:

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

Therapeutic Group: A combination of antibiotics of the penicillins family and a local anesthetic.

4. Contraindications:

Do not inject intravenously or intrathecally.

Do not use in known cases of hypersensitivity to penicillins.

Not to be used in very small herbivores such as guinea pigs, gerbils and hamsters.

5. Adverse reactions:

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.

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

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting adverse events due to drug treatment" found on the home page of the Ministry of Health website (www.health.gov.il) which refers to the online form for reporting adverse events, or by entering the link: <https://sideeffects.health.gov.il/>

6. Target species:

Cattle, sheep, pigs

7. Amounts to be administered and administration route:

Administer by deep intramuscular injection only.

The recommended dose rate is:

10 mg/kg bodyweight (1 ml/30 kg) daily for 3 to 5 days.

Care should be taken not to overdose.

8. How to use the preparation:

Shake the container before use.

9. Withdrawal period:

Meat and offal: Cattle, sheep, pigs: 7 days.

Milk: Cattle: 72 hours.

Do not use in sheep producing milk for human consumption.

10. Special warnings and precautions for use:

• 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.

• Special precautions for use in animals:

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.

• 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.

- Do not handle this product if you know you are sensitized to such preparations.
- Handle this product with great care to avoid exposure, taking all recommended precautions.
- If you develop symptoms following exposure such as 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.

• Additional precautions:

None

• 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.

• Interaction with other medicinal products and other forms of interaction:

None known.

• Overdose:

Penicillins show a wide margin of safety.

• Incompatibilities:

None known.

11. Storage instructions:

- Prevent poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and / or infants and thereby prevent poisoning.
- Do not use this medicine after the exp. date on the package. The expiration date refers to the last day of that month.
- Storage conditions:**
Store in a refrigerator (2°C – 8°C).
Protect from light.
- After first opening of the packaging, the product should be used up within 28 days. Remains of the product should be discarded after 28 days.

12. 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 as toxic waste. Do not dispose in sewage.

13. FURTHER INFORMATION:

• In addition to the active ingredient the product also contains:

Nipasept (Methyl Parahydroxybenzoate, Ethyl Parahydroxybenzoate, Propyl Parahydroxybenzoate), Potassium Chloride, Povidone K12, Disodium Edetate Dihydrate, Potassium Acid Phosphate, Sodium Citrate Dihydrate, Polysorbate 80, Antifoam M30, Water for Injection.

• Pharmaceutical form:

A white to off-white suspension.

• Packaging size:

50 ml, 100 ml and 500 ml glass vials.

Not all pack sizes may be marketed.

• **Registration holder:** Abic Veterinary Products Ltd., 2 Hanegev Street, Airport City, 7019900

• **Manufacturer:** Norbrook Laboratories Limited, Station Works, Camlough Road, Newry, Co. Down, BT35 6JP, Northern Ireland, UK.

Revised in July 2025 according to MoH's guidelines.

• **Registration number of the medicine in the National Registry of the Ministry of Health:** 083-40-92360-00