

Veterinary Medicine User Leaflet
Veterinarian Prescription Only Medicine
For Animal Use Only

1. NAME AND FORM OF THE VETERINARY MEDICINE:
Pen & Strep Veterinary, Suspension for Injection

2. ACTIVE INGREDIENTS:

Each 1 ml of the medicine contains:

<i>Procaine Penicillin</i>	<i>200 mg</i>
<i>Dihydrostreptomycin Sulphate</i>	<i>250 mg</i>

The medicine also contains the excipients:

Hydroxybenzoate Esters (as Nipasept Sodium) 1.5mg as antimicrobial preservative.

Sodium Formaldehyde Sulphoxylate dihydrate 1.25mg as antioxidant.

For a full list of excipients, see section 13 "Further Information".

3. Indications for use:

Treatment of infection caused by or associated with organisms sensitive to penicillin and/or streptomycin in cattle, horses, pigs and sheep.

Therapeutic group: Antibacterials for systemic use.

4. Contraindications:

Contraindicated in known cases of hypersensitivity to penicillins.

5. Adverse reactions:

In rare cases, hypersensitivity reactions can occur and very rarely, these can be fatal.

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

A palpable but transient local reaction may occur at the site of intramuscular administration in horses.

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, horses, pigs, sheep.

7. Amount to be administered and administration route:

Administer by deep intramuscular injection.

Recommended dosage rate is 8 mg/kg bodyweight procaine penicillin with

10 mg/kg bodyweight dihydrostreptomycin sulphate equivalent to 1 ml / 25 kg bodyweight.

Treatment should be given once daily for up to 3 consecutive days.

8. How to use the product:

Shake the vial before use.

The maximum dose volume administered at one site should not exceed: 15 ml for horses, 6 ml for cattle, 3 ml for sheep and 1.5 ml for pigs.

9. Withdrawal period:

Not to be used in sheep producing milk for human consumption.

Not to be used in horses intended for human consumption.

Milk for human consumption must not be taken during treatment and for 48 hours after the last treatment.

Animals must not be slaughtered for human consumption during treatment and for 14 days after the last treatment.

10. Warnings:

• Special precautions regarding the use of the medicine for the target animals:

Use with care in animals known to have kidney disease or defective renal function.

Do not exceed the recommended dosage or duration of treatment.

• Special safety precautions regarding the use of the medicine in animals:

None.

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

Care should be taken to avoid accidental self-injection. In the case of accidental self-injection, seek medical advice immediately.

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 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 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 in breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

• Additional precautions:

None.

• Use during pregnancy and lactation:

Pen & Strep 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.

- Interactions with other medicinal products and other forms of interactions:
Do not administer with other antibiotics such as tetracyclines or with other aminoglycosides.
- Overdose:
No treatment specified.
- 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 the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of the month.
- Storage conditions:
Store in a refrigerator (2°C – 8°C).
Protect from light.
- After first opening of the package, 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 products 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 as toxic waste. Do not dispose of sewage.

13. Further information:

- In addition to the active ingredients the medicine also contains:
Polyvinylpyrrolidone, Polysorbate 80, Lecithin, Sodium Citrate, Disodium Edetate, Procaine Hydrochloride, Sodium Formaldehyde Sulphoxylate, Cetrimide, Nipasept (as sodium salt), Citric Acid, Potassium Chloride, Water for Injection.
- Pharmaceutical form:
A white to off-white aqueous suspension for injection.
- Packaging size:
Supplied in 100 ml clear type II glass vials, sealed with bromobutyl rubber bungs and aluminium caps.
- **Registration holder and address:**
Comex Ltd., 1 Nablus Road, P.O.B. 19943, Jerusalem, 97200
- **Manufacturer and address:**
Norbrook Laboratories Limited, Station Works, Camlough Road, Newry, Co. Down, BT35 6JP, Northern Ireland, UK

Revised in April 2023 according to MoH's guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 081-64-92222-00