## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pen & Strep Suspension for Injection

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

**Active substances:**
200 mg Procaine Benzylpenicillin and Dihydrostreptomycin Sulphate equivalent to 200 mg Dihydrostreptomycin

**Excipients:**

| **Qualitative composition of excipients and other constituents** | **Quantitative composition if that information is essential for proper administration of the veterinary medicinal product** |
|---|---|
| Methyl, ethyl and propyl parahydroxybenzoate as sodium salts (as preservative) | 1.5 mg |
| Sodium formaldehyde sulfoxylate (as antioxidant) | 1.25 mg |
| Disodium edetate | |
| Povidone K12 | |
| Polysorbate 80 | |
| Sodium citrate | |
| Lecithin | |
| Procaine hydrochloride | |
| Cetrimide | |
| Potassium chloride | |
| Water for injections | |

A white to off-white suspension for injection.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cattle, sheep, pigs

### 3.2 Indications for use for each target species

For the treatment of systemic infections caused by or associated with organisms sensitive to penicillin and/or streptomycin including:

*Corynebacterium pyogenes*
*Erysipelothrix rhusiopathiae*
*Klebsiella pneumoniae*
*Listeria* spp

*Pasteurella haemolytica*
*Pasteurella multocida*
*Staphylococcus* spp. (non-penicillinase producing)
*Streptococcus* spp.

The veterinary medicinal product will therefore be effective in the treatment of infections caused by susceptible organisms including: erysipelas; navel/joint ill; respiratory tract infections, including pneumonia and atrophic rhinitis; listeriosis, meningitis; septicaemia; toxaemia associated with mastitis; urogenital tract infections; enteritis and the control of secondary bacterial invaders in diseases of primary viral origin.

**3.3 Contraindications**

Not for intravenous administration.
Do not use in sheep producing milk for human consumption.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

**3.4 Special warnings**

None.

**3.5 Special precautions for use**

Special precautions for use in animals

Administer by deep intramuscular injection only.

Special precautions to be taken by the person administering the 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. People with known hypersensitivity to penicillin and cephalosporins should avoid contact with the veterinary medicinal product.

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 and eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Special precautions for the protection of the environment:

Not applicable.

**3.6 Adverse events**

Target species: Cattle, sheep, pigs.

| | |
|---|---|
| Rare<br>(1 to 10 animals / 10,000 animals treated): | Hypersensitivity reaction[1],<br>Anaphylaxis[1] |

[1]Sometimes fatal.

Target species: Pigs

| | |
|---|---|
| Rare<br><br>(1 to 10 animals / 10,000 animals treated): | Vomiting[1];<br>Pyrexia[1, 3], Listless[1];<br>Shivering[1], Incoordination[1];<br>Vaginal discharge[2] |

[1] In suckling and fattening pigs.
[2] In pregnant sows and gilts, which could be associated with abortion.
[3] Transient

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

### 3.8 Interaction with other medicinal products and other forms of interactions

None known.

### 3.9 Administration routes and dosage

Shake well before use.
Administer by deep intramuscular injection.
The stopper should not be punctured more than 25 times.
Recommended dosage rate is as follows: 8 mg/kg bodyweight procaine penicillin and 10 mg/kg bodyweight dihydrostreptomycin sulphate achieved by administering 1 ml per 25 kg bodyweight. The dose should be given once daily for up to 3 consecutive days.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

### 3.12 Withdrawal period(s)

Milk for human consumption must not be taken during treatment.
Animals must not be slaughtered for human consumption during treatment.

Cattle:
Milk: 48 hours.
Meat and offal: 21 days.

Sheep:
Meat and offal: 28 days.
Not authorised for use in ewes producing milk for human consumption.

Pigs:
Meat and offal: 18 days.

## 4. PHARMACOLOGICAL INFORMATION

**4.1 ATCvet Code:** QJ01RA01

### 4.2 Pharmacodynamics

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.

Dihydrostreptomycin is an aminoglycoside antibiotic which after penetration of the cell envelope binds to receptors on the 30s subunit of the ribosome. It induces misreading of the genetic code on the messenger ribonucleic acid (mRNA) template.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

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

### 5.2 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.

### 5.3 Special precautions for storage

Store in a refrigerator (2°C and 8°C).

Keep the vial in the outer carton in order to protect from light.

### 5.4 Nature and composition of immediate packaging

Multidose 50 ml and 100 ml uncoloured Type II (Ph. Eur.) glass vial and 50 ml, 100 ml and 250 ml plastic (PET) vials containing a white to off-white sterile suspension, sealed with a bromobutyl rubber stopper and aluminium cap, in outer cartons of one vial.

Not all pack sizes may be marketed.

## 5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

## 7. MARKETING AUTHORISATION NUMBER(S)

VPA22664/009/001

## 8. DATE OF FIRST AUTHORISATION

01/10/1987

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

30/05/2024

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).