1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pro Penstrep suspension for injection for cattle, sheep and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Procaine benzylpenicillin	200 mg
Dihydrostreptomycin	200 mg (as dihydrostreptomycin sulphate)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate	1.0 mg
Sodium formaldehyde sulfoxylate	0.432 mg
Simethicone emulsion	
Sodium citrate	
Potassium dihydrogen phosphate	
Disodium edetate	
Povidone K12	
Water for injections	

A white to off-white aqueous suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, sheep and pigs.

3.2 Indications for use for each target species

For the treatment of infections caused by bacteria sensitive to penicillin and dihydrostreptomycin in cattle, sheep and pigs.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use when it is known that penicillinase-producing staphylococcus organisms are present.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of this veterinary medicinal 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 (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Whenever possible the veterinary medicinal product should only be used on the basis of susceptibility testing.

Special precautions to be taken by the person administering the veterinary 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 can occasionally be serious.

1. Do not handle this veterinary medicinal product if you know you are sensitised or if you have been advised not to work with such preparations.
2. Handle this veterinary medicinal 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 package leaflet or the label to the physician. 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

Cattle, sheep and pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction (allergic reactions)[1]

[1] can vary from localised swelling to anaphylaxis and death.

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	vaginal discharge[1], incoordination, pyrexia[2,3], vomiting[2], shivering[2], listless[2,] appetite loss[2], cyanosis[2,4]

[1] In pregnant sows and gilts, which could be associated with abortion.
[2]Procaine penicillin G can, under certain circumstances, be toxic and even lethal to pigs and this is thought to be due to a sudden release of toxic amounts of free procaine.
[3]40℃ and over.
[4]of the extremities.

Alarming side-effects are most likely to occur when pigs with erysipelas are injected with an older and/or, heat-affected procaine penicillin formulation. Treatment with 5 mg dexamethasone will result in rapid recovery.

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 its local representative or the national competent authority via the national reporting system.
See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Procaine penicillin and dihydrostreptomycin are safe for use in pregnant animals.
Not for use in lactating ewes producing milk for human consumption.

3.8 Interaction with other medicinal products and other forms of interaction

Tetracyclines are bacteriostatic antibiotics that may interfere with a bactericidal agent such as

penicillin. Since
penicillin acts by inhibiting cell wall synthesis, agents such as tetracyclines, which inhibit protein synthesis, could mask the bactericidal effect of penicillin.

If penicillin is used with a tetracycline, it would be prudent to observe the following points when possible:

1. Be sure adequate amounts of each agent are given; antagonism is most likely to occur when barely sufficient amounts of each agent are given.
2. Begin administration of the penicillin at least a few hours before the administration of tetracycline.

3.9 Administration routes and dosage

The recommended dose is 4 ml per 100 kg bodyweight i.e. 8 mg procaine penicillin and 10 mg dihydrostreptomycin sulphate per kg. The dose should be given once daily for up to 3 consecutive days.

To ensure a correct dosage bodyweight should be determined as accurately as possible to avoid under-dosing.

For intramuscular administration only.

Species	**Dose (ml)**	**kg Bodyweight**
Cattle	4.0	100
Calf	2.0	50
Sheep	1.0	25
Lamb	0.4	10
Sow	3.0	75
Piglet	0.2	5

Clean the area of injection and swab with spirit.

The maximum dose volume recommended at any one site for Cattle is 20 ml.
Administer alternately on the left and the right side.

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

Do not exceed the stated dose.

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 periods

Cattle:
Meat and offal: 21 days.
Milk: 72 Hours.

Sheep:
Meat and offal: 21 days.
Milk: Not to be used in lactating ewes producing milk for human consumption.

Pigs:

Meat and offal: 21 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01RA01

4.2 Pharmacodynamics

Penicillins are rapidly absorbed when injected in an aqueous suspension by the intramuscular route. However, absorption of Penicillin G from a procaine penicillin preparation is prolonged, with peak blood levels being attained at approximately 2-4 hours and declining below therapeutic levels at 24 hours on pigs and 48 hours in cattle and sheep.

Dihydrostreptomycin is also absorbed rapidly. Peak plasma concentration occurs within 1 hour. The blood levels will decline a lot faster (below therapeutic levels at 12 hours) than the Penicillin G due to a slower absorption of the penicillin from the procaine preparation.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

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 – 8 °C).
Do not freeze.

5.4 Nature and composition of immediate packaging

Type II siliconised clear glass, 50 ml and 100 ml vials closed with nitryl rubber stoppers and sealed with aluminium seals.

Pack sizes:
50 ml,
100 ml,
12 x 100 ml vials in a cardboard/polystyrene box.

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

Interchem Ireland Ltd

7. MARKETING AUTHORISATION NUMBER(S)

VPA10555/007/001

8. DATE OF FIRST AUTHORISATION

10/02/2012

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

04/02/2025

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).