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 substance:

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

Excipients:

Methyl parahydroxybenzoate (E218)	1.0	mg
Sodium formaldehyde sulfoxylate	0.432	mg

For the full list of excipents, see section 6.1

3 PHARMACEUTICAL FORM

Suspension for injection. A white to off-white aqueous suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, Sheep, Pigs.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not administer to animals known to be sensitive to penicillin. Do not use when it is known that penicillinase-producing staphylococcus organisms are present.

4.4 Special warnings for each target species

Occasionally in sucking and fattening pigs in administration of products containing procaine penicillin may cause a transient pyrexia, vomiting, shivering, listlessness and incoordination.
In pregnant sows and gilts a vulval discharge which could be associated with abortion has been reported.
The maximum dose volume recommended at any one site for Cattle is 20 ml.

4.5 Special precautions for use

Special precautions for use in animals:
Use of this 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 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 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 and eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

Occasional allergies to penicillins have been observed but these are very rare. Hypersensitivity (allergic) reactions to penicillins can vary from localised swelling to anaphylaxis and death.
Occasionally in sucking and fattening pigs, administration of products containing procaine penicillin may cause a transient pyrexia, vomiting, shivering, listlessness and incoordination.
In pregnant sows and gilts a vulval discharge which could be associated with abortion has been reported. 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. The symptoms include shivering, lassitude, inappetence, vomiting, cyanosis of the extremities and pronounced pyrexia (40°C and over). A vulval discharge may appear and some animals may abort. 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.

4.7 Use during pregnancy, lactation or lay

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

4.8 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 adaquate 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.

4.9 Amounts to be administered and administration route

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.

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

Do not exceed the stated dose.

4.11 Withdrawal period(s)

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QJ01RA01 Pharmacotherapeutic Group: Penicillins, combinations with other antibacterials

5.1 Pharmacodynamic properties

Antibacterial

5.2 Pharmacokinetic particulars

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 leavels at 24 hours on pigs and 48 hours in cattle and sheep. Dihyrdostreptomycin 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybezoate (E218)
Sodium formaldehyde sulfoxylate
Simethicone emulsion
Sodium citrate
Potassium dihyrdogen phosphate
Disodium edetate
Povidone K12
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years Shelf life after first opening the immediate packaging: 4 weeks.

6.4 Special precautions for storage

Store in a refrigerator (2^{o}C - 8^{o}C).
Do not freeze.

6.5 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.
Not all pack sizes may be marketed.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Interchem Ireland Ltd
29 Cookstown Industrial Estate
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10555/007/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th February 2012
Date of latest renewal: 22nd December 2017

10 DATE OF REVISION OF THE TEXT

December 2017