1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Propen 300 mg/ml Suspension for Injection for Cattle, Sheep and Pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active Substance
Benzylpenicillin Procaine 300 mg
Excipient (preservative)
Methyl Parahydroxybenzoate (E218) 1 mg
For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

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

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, sheep and pigs.

4.2 Indications for use, specifying the target species

For the treatment of infections caused by bacteria sensitive to penicillins 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 administration of products containing procaine penicillin may cause a transient pyrexia, vomiting, shivering, listlessness and incordination.
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 extemities and pronounced pyrexia (40ºC 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.

4.5 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.

4.7 Use during pregnancy, lactation or lay

Procaine penicillin is safe for use in pregnant animals.
Not for use in lactating ewes producing milk for human consumption or milk products.

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.

4.9 Amounts to be administered and administration route

The recommended dose is 8 ml per 100 kg bodyweight i.e. 24 mg procaine penicillin per kg bodyweight.

For intramuscular administration only.
The dose should be given once daily for up to 3 consecutive days.

Species	Dose (ml)	Kg Bodyweight
Cattle	8.0	100
Calf	4.0	50
Sheep	2.0	25
Lamb	0.8	10
Sow	6.0	75
Piglet	0.4	5

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: 7 days
Milk: 72 hours

Sheep:
Meat and offal: 7 days
Milk: Not for use in lactating ewes producing milk for human consumption.

Pigs:
Meat and offal: 7 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Antibacterials for systemic use, procaine penicillin
ATCvet Code: QJ01CE09

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 in pigs and 48 hours in cattle and sheep.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate (E218)
Povidone K 12
Disodium edetate
Sodium citrate
Potassium dihydrogen phosphate
Simethicone emulsion
Water for injection

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: 28 days.

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze.

6.5 Nature and composition of immediate packaging

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

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 10555/009/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th March 2012
Date of last renewal: 12th January 2017

10 DATE OF REVISION OF THE TEXT

January 2018