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

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 (E218)	1 mg
Povidone K12	
Disodium edetate	
Sodium citrate	
Potassium dihydrogen phosphate	
Simethicone emulsion	
Water for injection	

A white to off-white 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 penicillins in cattle, sheep and pigs.

3.3 Contraindications

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

3.4 Special warnings

Occasionally in sucking and fattening pigs' administration of products containing procaine penicillin may cause a transient pyrexia, vomiting, shivering, listlessness and incoordination.

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.

After absorption, benzylpenicillin poorly penetrates biological membranes (e.g., blood-brain barrier) since it is ionised and poorly lipid soluble. Use of the product for treatment of meningitis or CNS infections due to e.g., *Streptococcus suis* or *Listeria monocytogenes* may not be efficacious. Furthermore, benzylpenicillin penetrates mammalian cells poorly and hence this product may have little effect in treating intracellular pathogens e.g., *Listeria monocytogenes*.

Elevated MIC values or bi-modal distribution profiles suggesting acquired resistance have been reported for the following bacteria:
- *Glaesserella parasuis*, *Staphylococcus* spp. causing MMA/PPDS, *Streptococcus* spp. and *S. suis* in pigs.
- *Fusobacterium necrophorum* causing metritis and *Mannheimia haemolytica* (only in some member states), as well as *Bacteroides* spp., *Staphylococcus chromogenes*, *Actinobacillus lignieresii* and *Trueperella* pyogenes in cattle.

Use of the veterinary medicinal product may result in a lack of clinical efficacy when treating infections caused by these bacteria.

3.5 Special precautions for use

Special precautions for safe use in the target species

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. 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 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 reaction[1]

[1]Varying in severity from localised swelling to anaphylaxis to death.

Systemic toxic effects have been observed in young piglets, which are transient but can be potentially lethal, especially at higher doses.

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy.
Not for use in lactating ewes producing milk for human consumption or milk products.

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.

3.9 Administration routes and dosage

The recommended dose is 8 ml per 100 kg bodyweight i.e. 24 mg procaine penicillin per kg bodyweight.
To ensure a correct dosage, body weight should be determined as accurately as possible.

For intramuscular administration only.
Shake well before use.

The dose should be given once daily. The treatment duration is 3 to 7 days.
The appropriate treatment duration should be chosen based on the clinical needs and individual recovery of the treated animal. Consideration should be given to the accessibility of the target tissue and characteristics of the target pathogen.

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 side 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 period(s)

Cattle:
Meat and Offal: 7 days for treatment duration 3 days.
9 days for treatment duration 4 – 7 days.
Milk: 72 hours.

Sheep:
Meat and Offal: 7 days for treatment duration 3 days.
9 days for treatment duration 4 – 7 days.

Milk: Not for use in lactating ewes producing milk for human consumption.

Pigs:
Meat and Offal: 7 days for treatment duration 3 days.
9 days for treatment duration 4 – 7 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATC Vet Code: QJ01CE09.

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 in pigs and 48 hours in cattle and sheep.

Enterobacterales, *Bacteroides fragilis*, most *Campylobacter* spp., *Nocardia* spp. and *Pseudomonas spp*. as well as beta-lactamase–producing *Staphylococcus* spp. are resistant.

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 to 8°C).
Do not freeze.

5.4 Nature and composition of immediate packaging

Type II (Ph. Eur.) siliconised uncoloured glass 100 ml vial closed with a nitryl rubber stopper and sealed with an aluminium seal.

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

VPA 10555/009/001

8. DATE OF FIRST AUTHORISATION

30/03/2012

9. DATE OF THE LAST REVISION OF THE SUMMARY OF 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).