1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Promox LA 150 mg/ml suspension for injection for cattle, sheep and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:

Amoxicillin (as Amoxicillin Trihydrate) 150 mg

Excipients:

Qualitative composition of excipients and other constituents
Aluminium Di-stearate
Medium Chain Triglycerides

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

The veterinary medicinal product is used for the treatment of diseases caused by a wide range of Gram-positive and Gram-negative organisms including:

Clostridium spp., *Corynebacterium* spp*., Erysipelas* spp*., Fusiformis* spp*., Haemophilus* spp*., Pasteurella* spp., *Salmonella* spp*., Streptococci* and *Staphylococci*.

Specific indications - Pneumonia, skin and soft tissue infections, abscesses, wounds, joint/navel ill.

3.3 Contraindications

Not for intravenous administration.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

Massage the injection site after administration. In adult cattle, the volume should be divided between two injection sites.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the 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.

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:

Undetermined frequency (cannot be estimated from the available data):	Injection site irritation
Rare (1 to 10 animals / 10,000 animals treated):	Allergic reaction[1]

[1] Reactions to penicillins can vary from localised swelling to anaphylaxis and death. Therapy involves hot- or cold- water soaks and/or corticosteroids.

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:

Can be used during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

Tetracyclines are bacteriostatic antibiotics that presumably may interfere with a bactericidal agent such as amoxicillin. Since amoxicillin acts by inhibiting cell wall synthesis, agents such as tetracyclines, which inhibit protein synthesis, could mask the bactericidal effect of amoxicillin.

3.9 Administration routes and dosage

For deep intramuscular use only.
The recommended dose rate is 15 mg per kg bodyweight i.e. 1 ml per 10 kg.
To ensure a correct dosage body weight should be determined as accurately as possible.

Species	Dose ml per kg bodyweight
Cattle	10.0 ml / 100 kg
Calf	5.0 ml / 50 kg
Sheep	2.5 ml / 25 kg
Lamb	1.0 ml / 10 kg
Sow	7.5 ml / 75 kg
Piglet	0.5 ml / 5 kg

The dose may be repeated every 36 hours in pigs and 48 hours in cattle and sheep for up to 4 days.
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

Meat and offal: 28 days.
Milk: 120 hours (5 days).

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01CA04

4.2 Pharmacodynamics

4.3 Pharmacokinetics

Therapeutic plasma levels are maintained for 36 hours in pigs and 48 hours in cattle and sheep.

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: 3 years.

Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 25°C. Do not freeze. Protect from light.

5.4 Nature and composition of immediate packaging

100 ml clear, type II, glass vial closed with a nitryl stopper and 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(S)

VPA 10555/010/001

8. DATE OF THE FIRST AUTHORISATION

08 June 2012

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

04 September 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*).