1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Promox LA 150 mg/ml Suspension for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active Substance

Amoxicillin (as Amoxicillin Trihydrate) 150 mg

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

A white to off white suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, sheep and pigs

4.2 Indications for use, specifying the target species

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
Staphylococci.

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

4.3 Contraindications

Not for intravenous administration.

Do not use in animals with known hypersensitivity to the active ingredients.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals
Use of the 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 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 local reaction may occur.
Occasional allergies to the penicillins have been observed but these are rare.

4.7 Use during pregnancy, lactation or lay

Amoxicillin is safe for use in pregnant animals.

4.8 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.

4.9 Amounts to be administered and administration route

For deep intramuscular injection 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.

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

Do not exceed the stated dose. Hypersensitivity (allergic) reactions to penicillins can vary from localized swelling to anaphylaxis and death. Therapy involves hot- or cold-water soaks and/or corticosteroids.

4.11 Withdrawal period(s)

Meat and offal: 28 days
Milk: 120 hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Phamacotherapeutic group: Antibacterial for systemic use, amoxicillin.
ATCvet code: QJ01CA04

5.1 Pharmacodynamic properties

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium Di-stearateMedium Chain Triglycerides

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: 3 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. Protect from light.

6.5 Nature and composition of immediate packaging

100 ml clear, type II, glass vial closed with a nitryl stopper and aluminium seal.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Interchem Ireland Ltd
29 Cookstown Industrial Estate
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10555/010/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th June 2012
Date of last renewal: 26th January 2018

10 DATE OF REVISION OF THE TEXT

January 2018