

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Alfamox LA 150 mg/ml Suspension for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance

Amoxicillin 150 mg
(as Amoxicillin Trihydrate)

Excipients

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

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.

Streptococci spp.

Salmonella spp.

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 ingredient.

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 precaution(s) 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	7.5ml/75Kg
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)

Cattle, sheep and pigs: Meat and offal: 28 days

Cattle and sheep: Milk: 120 hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, amoxicillin.

ATCvet code QJ01CA04

5.2 Pharmacokinetic particulars

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-stearate
Miglyol (Fractionated Coconut Oil)

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

Shelf life after opening the immediate packaging: 4 weeks

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

Off-white oily suspension presented in 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

Alfa Med Limited
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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10894/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21st January 2009

10 DATE OF REVISION OF THE TEXT

July 2018