SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clamoxyl Long Acting 150 mg/ml Suspension for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients:	*mg/ml*
Amoxicillin (As Amoxicillin trihydrate)	150

For a full list of excipients please see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection.
White to off-white oily suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep, dogs and cats

4.2 Indications for use, specifying the target species

The product is a broad-spectrum semi-synthetic penicillin which is bactericidal *in vitro* against a wide range of Gram-positive and Gram-negative bacteria including the following:

Gram-negative:

Actinobacillus lignieresi; Bordetella bronchiseptica, Escherichia coli (non beta-lactamase producing strains), Corynebacterium spp.; Fusobacterium spp.; Haemophilus spp.; Moraxella spp.; Pasteurella spp.; *Proteus mirabilis* (non beta-lactamase producing strains); Salmonella spp.

Gram-positive:

Bacillus anthracis; Clostridium spp.*; Erysipelothrix rhusiopathiae;* Streptococci; Staphylococci (non beta-lactamase producing strains).

The product is suitable for the control of infections caused by susceptible organisms in sheep, dogs and cats where prolonged activity from a single injection is required. It may also be used to control secondary bacterial invasion in conditions where bacteria are not a primary cause of disease.

Particular indications for the product are:

1. Alimentary tract infections, including enteritis
2. Respiratory tract infections.
3. Urogenital tract infections, including cystitis and metritis
4. Skin and soft tissue infections, including wounds, abscesses, foot infections, joint and navel ill.
5. Prevention of post-operative infections by injection prior to surgery.

4.3 Contra-indications

In common with all other penicillins, amoxicillin should not be used orally or parenterally in rabbits, guinea pigs, hamsters or gerbils. Caution is advised in its use in any other very small herbivores. The product is not suitable for intravenous injection.

Although preruminants such as lambs may be treated orally or parenterally, animals possessing a functional rumen should only be treated parenterally.

4.4 Special warnings for each target species

Do not use in animals with known sensitivity to the active substance.

The product is not effective against beta-lactamase producing organisms.

Complete cross-resistance has been shown between amoxicillin and other penicillins, in particular amino-penicillins.
Use of the product/amoxicillin should be carefully considered when antimicrobial susceptibility testing has shown resistance to penicillins because its effectiveness may be reduced.

4.5 Special precautions for use

i) Special precautions for use in animals

Shake vial before use. The product does not contain an antimicrobial preservative. Swab the septum before removing each dose. Since amoxicillin hydrolyses rapidly in the presence of water, it is important that a dry sterile needle and syringe is used when withdrawing the suspension to avoid contaminating the remaining suspension with drops of water.

Do not broach more than 40 times.

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 epidemiological information.

ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

Care should be taken to avoid accidental self-injection.

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and vice versa. Allergic reaction to these substances may occasionally be serious.

Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
Handle this product with great care to avoid exposure taking all recommended precautions.

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, or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Use of the product may occasionally result in local tissue reaction.
Penicillins and cephalosporins may cause hypersensitivity (allergy, allergic skin reactions) after use. Allergic reactions may occasionally be serious (anaphylaxis).
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

the product is indicated for use in pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

It is not generally recommended to use bactericidal and bacteriostatic antibiotics at the same time.
Beta-lactam antibiotics are known to interact with antibiotics with bacteriostatic action such as chloramphenicol, macrolides, sulfonamides and tetracyclines.
There is also synergic action of penicillins with aminoglycosides.

4.9 Amounts to be administered and administration route

The product is intended for use via the intramuscular or subcutaneous routes in cats and dogs and via the intramuscular route only in sheep.

Dosage rate: the recommended dosage rate is 15 mg/kg which is equivalent to 1.0 ml/10 kg bodyweight. The dose may be repeated after 48 hours.

Use a new anatomical site for repeated injections.

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid overdosing.

Dosing guide:
The following table gives examples of doses for the different species.

Animal	Specimen Weight (kg)	Dose (ml)
Sheep	65	6.5
Lamb	10	1.0
Dog large	35	3.5
medium	20	2.0
small	10	1.0
Cat	5	0.5

Shake the vial well before use. Inject by the intramuscular route, then massage the injection site. (For ease of administration in dogs and cats, needles no finer than 20 gauge should be used). If the volume to be given is greater than 5 ml (sheep) it should be divided and injected into two separate sites. The suspension is not suitable for intravenous or intrathecal administration.

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

Amoxicillin is of a very low order of acute toxicity and is well tolerated by the parenteral route. Occasional injection site reactions may occur with the recommended dose, but no other adverse side-effects are to be expected from accidental overdosing.

4.11 Withdrawal period

Meat and offal: 45 days
Not to be used in sheep producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

ATCVet Code: QJ01CA04

Amoxicillin is a broad spectrum semi-synthetic penicillin that is bactericidal against a wide range of Gram-positive and Gram-negative pathogens.

The following features of the product warrant special mention:

- After absorption, amoxicillin is widely distributed throughout body tissues, with especially high levels in the kidneys, urine, liver and bile.

- In respiratory infections, amoxicillin crosses inflamed pulmonary membranes into mucus. As the disease responds and associated inflammation recedes, amoxicillin levels are maintained in the mucus thus preventing recrudescence of the original infection.

- Amoxicillin is very rapidly bactericidal. At a concentration of 10 µg/ml *Escherichia coli* is completely lysed in only 1 hour, *in vitro*.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium distearate
Fractioned coconut oil

6.2 Incompatibilities

None known

6.3 Shelf-life

Shelf-life of the 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.
Following withdrawal of the first dose, use the product within 28 days.
Discard unused material.

6.5 Nature and composition of immediate packaging

Carton containing either 6 x 100 ml or 4 x 250 ml clear colourless type III glass vials with rubber nitrile bungs with aluminium overseals.

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

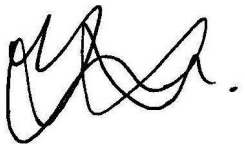
Vm 42058/4013

9. DATE OF THE FIRST AUTHORISATION

28 January 1998

10. DATE OF REVISION OF THE TEXT

April 2022



Approved: 08 April 2022