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Clamoxyl Long Acting 150 mg/ml Suspension for Injection

Species: Sheep, Cats, Dogs

Therapeutic indication:Pharmaceuticals: Antimicrobials: Injections

Active ingredient: Amoxicillin Trihydrate

Product: Clamoxyl® LA Suspension for Injection

Product index: Clamoxyl LA

Sheep - meat:45 days

Incorporating:

Presentation

Clamoxyl Long Acting 150 mg/ml Suspension for Injection is a white to off-white oily suspension containing 150 mg/ml amoxicillin as Amoxicillin trihydrate.

The formulation is designed to provide effective antibiotic activity over a period of 48 hours.

Uses

Clamoxyl 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	Gram-Positive
Actinobacillus lignieresi	*Bacillus anthracis*
Bordetella bronchiseptica	*Clostridium* spp.
Escherichia coli	*Corynebacterium* spp.
Fusobacterium spp.	Erysipelothrix rhusiopathiae
Haemophilus spp.	streptococci and staphylococci (penicillin sensitive strain

Moraxella spp.

Pasteurella spp.

Proteus mirabilis

Salmonella spp.

Clamoxyl Long Acting Suspension for Injection 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 Clamoxyl L.A. Injection are:

1Alimentary tract infections, including enteritis.

2Respiratory tract infections.

3Urogenital tract infections, including cystitis and metritis.

4Skin and soft tissue infections, including wounds, abscesses, foot infections, joint and navel ill.

5Prevention of post-operative infections by injection prior to surgery.

Dosage and administration

The recommended dosage rate is 15 mg/kg bodyweight, which is equivalent to 1 ml/10 kg. If necessary, the dose may be repeated after 48 hours.

The following is intended as a guide

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

Shake the vial well before use. Inject by the subcutaneous or intramuscular route (dogs and cats) or the intramuscular route only (sheep), 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.

In common with other penicillin preparations, hydrolysis takes place rapidly in the presence of water. It is important, therefore, that a dry syringe is used when extracting suspension for injection, to avoid contaminating the remaining contents of the vial with drops of water. Do not broach the vial more than 40 times.

Contra-indications, warnings, etc

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 epidemiological information.

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 pre-ruminants such as lambs may be treated orally or parenterally, animals possessing a functional rumen should only be treated parenterally.

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.

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).

Withdrawal periods

Sheep meat: 45 days

Not for use in sheep producing milk for human consumption.

Operator warnings

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 reactions 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.

Pharmaceutical precautions

Do not store above 25°C.

This product does not contain an antimicrobial preservative. Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

Any unused product or waste materials should be disposed of in accordance with local requirements.

Keep out of the sight and reach of children.

For animal treatment only.

Legal category

Legal category:POM-V

Packaging quantities

Clamoxyl Long Acting Suspension for Injection is available in packs containing 6 x 100 ml and 4 × 250 ml vials. Not all pack sizes may be marketed.

Further information

The following features of Clamoxyl L.A. Injection warrant special mention:

1After absorption, amoxicillin is widely distributed throughout body tissues, with especially high levels in the kidneys, urine, liver and bile.

2In 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.

3Amoxicillin shares with other penicillins the virtual absence of toxicity problems even at very high dose levels.

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.

NOAH Compendium

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.

Marketing Authorisation Number

Vm 42058/5228

Significant changes

GTIN

GTIN description:100 ml:

GTIN:05414736055350