

Amoxycare LA Suspension for Injection 15% w/v

Introduction



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Presentation

Amoxycare LA Injection is an off white sterile suspension containing 150 mg/ml amoxicillin as Amoxicillin Trihydrate.

Chemically, amoxicillin is 6[D(-α -) amino-p-hydroxyphenylacetamido] penicillanic acid.

Also contains Butylated Hydroxyanisole 0.08mg/ml and Butylated Hydroxytoluene 0.08 mg/ml as antioxidants.

Uses

Amoxicillin is a broad spectrum semi-synthetic penicillin bactericidal in action for use in cattle, pigs, sheep, dogs and cats. *In vitro* it is effective against a wide range of Gram-positive and Gram-negative bacteria which include: *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus* species, *Salmonella*, *Staphylococci* and *Streptococci*.

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

Amoxycare LA Injection is suitable for the control of infections, due to susceptible micro-organisms, in cattle, sheep, pigs, dogs and cats where a single injection giving prolonged activity is required. It may also protect from secondary bacterial invasion in cases where bacteria are not the initial cause of the disease.

Indications include infections of:

- Alimentary tract.
- Respiratory tract,
- Skin and soft tissue,
- Urogenital tract and,
- In prevention of post-operative infection (treat before surgery).

Dosage and administration

Cattle, Sheep and Pigs: By intramuscular injection only.

Dogs and Cats: By subcutaneous or intramuscular injection.

The recommended dosage rate is 15 mg/kg bodyweight repeatable if necessary after 48 hours. Massage the injection site. A separate injection site should be used for each administration.

ANIMAL	WEIGHT kg	DOSAGE VOLUME ml
Cattle	450 kg	45.0 ml
Sheep	65 kg	6.5 ml
Pigs	150 kg	15.0 ml
Dogs	20 kg	2.0 ml
Cats	5 kg	0.5 ml

(Dose volume is equivalent to 1 ml per 10 kg bodyweight).

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing. If dose volume exceeds 20 ml, it should be divided and injected into two sites.

As with other injectable preparations, normal aseptic precautions should be observed. (Use dry syringe for extraction of suspension to avoid hydrolysis of amoxicillin). Massage the injection site.

An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

Contra-indications, warnings, etc

This product is not suitable for intravenous or intrathecal administration.

Milk for human consumption must not be taken from a cow during treatment. With cows milked twice daily, milk for human consumption must not be taken from 84 hours (i.e. at the 7th milking) after the last treatment. With other dosing routines, the basis of the veterinary surgeons advice should be that milk may be taken for human consumption only after the same time period from the last treatment (i.e. with three times daily milking, milk for human consumption may only be taken at the 10th milking).

Not for use in sheep producing milk for human consumption.

Animals must not be slaughtered for human consumption during treatment.

Cattle may be slaughtered for human consumption only after 23 days from the last treatment. Sheep and pigs may be slaughtered for human consumption only after 16 days from the last treatment.

Occasionally local tissue reaction may occur with use of Amoxycare LA.

Not effective against beta-lactamase producing organisms.

Amoxicillin, like other penicillins, should not be administered orally or parenterally in rabbits, hamsters, gerbils and guinea pigs.

Not for use in known cases of hypersensitivity to penicillins or cephalosporins.

Operator warnings - Penicillin/Cephalosporin Sensitivity

Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately. Penicillin 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.

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 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. Keep out of the reach of children. Protect from light.

Shake well before use. Following withdrawal of the first dose, use the product within 28 days.

Discard unused material. This product does not contain an antimicrobial preservative. Swab the septum before removing each dose. Use a dry, sterile needle and syringe.

When the container is breached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written on the space provided on the label.

Legal category

POM-V

Packaging Quantities

Multidose vials of 100 ml.

Disposal

Dispose of any unused product and empty container in accordance with guidance from your local waste regulatory authority.

Further information

Due to its wide distribution, after absorption, high levels of amoxicillin are found in kidney, urine, liver and bile.

Also important is the rapid bactericidal action.

Due to its mode of action amoxicillin prevents recrudescence of respiratory infections.

The absence of toxicity, shared with other penicillins, is also apparent.

Animals with functional rumens should only be treated parentally.

Marketing Authorisation Holder (if different from distributor)

Norbrook Laboratories Ltd, Northern Ireland

Marketing authorisation number

Vm 2000/4141.

GTIN (Global Trade Item No)

100ml Vial:

05055037400298