

## Amoxycare Suspension for Injection 15% w/v

### Introduction



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### Presentation

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

Chemically, amoxicillin is 6[D](- $\alpha$  -) amino p-hydroxyphenylacetamido] penicillanic acid. Also contains: Butylated Hydroxyanisole 0.08mg/ml and Butylated Hydroxytoluene 0.08 mg/ml, as antioxidants.

### Uses

Amoxycare Injection is a broad spectrum semisynthetic penicillin, bactericidal in action. *In vitro* it is effective against a wide range of Gram-positive and Gram-negative pathogenic bacteria which include: *Actinobacillus equuli*, *Actinobacillus lignieresii*, *Actinomyces bovis*, *Bacillus anthracis*, *Bordetella bronchiseptica*, *Clostridium* species, *Corynebacterium* species, *Erysipelothrix rhusiopathiae*, *Escherichia coli*, *Fusiformis* species, *Haemophilus* species, *Moraxella* species, *Pasteurella* species, *Proteus mirabilis*, *Salmonella* species, Staphylococci and Streptococci in cattle, sheep, pigs, dogs and cats.

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

### Dosage and administration

CATTLE, SHEEP AND PIGS: By Intramuscular injection only.

DOGS AND CATS: By subcutaneous or intramuscular injection.

The recommended dosage rate is 7 mg/kg bodyweight once a day for up to five days. Massage the **injection site**.

ANIMAL	WEIGHT kg	DOSE VOLUME ml
Cattle	450 kg	20.0 ml
Sheep	65 kg	3.0 ml
Pigs	150 kg	7.0 ml
Dogs	20 kg	1.0 ml
Cats	5 kg	0.25 ml

(Guide-dose volume is equivalent to 0.25 ml per 5 kg daily).

If dose volume exceeds 20 ml in cattle or 10 ml in sheep and pigs it should be divided and injected in two sites.

Normal aseptic precautions should be observed.

An appropriately graduated syringe should 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 administration via intravenous or intrathecal routes.

Milk for human consumption must not be taken from a cow during treatment. Milk for human consumption may only be taken after 24 hours from the last treatment.

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 18 days from the last treatment. Sheep may be slaughtered for human consumption only after 10 days from the last treatment. Pigs may be slaughtered for human consumption only after 16 days from the last treatment.

Occasional local tissue reaction may result from use of this product.

Not effective against beta-lactamase producing organisms.

As with other penicillins Amoxicillin should not be used in rabbits, hamsters, gerbils and guinea pigs.

*Operator warning - Penicillin/Cephalosporin sensitivity*

Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately. Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross reaction 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 breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

## Pharmaceutical precautions

Keep out of the reach of children. Do not store above 25°C. Shake bottle 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 for the first time, using the in-use shelf-life which is specified on this data sheet, 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.

## Disposal

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

## Legal category

POM-V

## Packaging Quantities

Multidose vials of 100 ml.

## Further information

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

In common with other penicillins an absence of toxicity is apparent even at high dose levels.

Animals with functional rumens should only be treated parenterally.

## Marketing Authorisation Holder (if different from distributor)

Norbrook Laboratories Ltd, Northern Ireland

## Marketing authorisation number

Vm 2000/4140.

## GTIN (Global Trade Item No)

100ml Vial:

05055037400304