

TRYMOX LA

Amoxicillin Trihydrate
150 mg/ml Suspension for Injection
for Cattle, Sheep, Pigs, Cats, Dogs



Indications:

For the treatment of infections of the alimentary tract, respiratory tract, urogenital tract, skin and soft tissue caused by bacteria susceptible to amoxicillin.

100ml bottle

SEE REVERSE SIDE FOR FULL INDICATIONS, ADMINISTRATION AND DOSAGE.

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PRESENTATION

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

Each ml of solution contains:

Active substance:

Amoxicillin 150 mg (equivalent to amoxicillin trihydrate 172 mg)

Excipients: For a full list of excipients, see SPC.

USES

For the treatment of infections of the alimentary tract, respiratory tract, urogenital tract, skin and soft tissue caused by bacteria susceptible to amoxicillin.

DOSAGE AND ADMINISTRATION

The recommended dosage rate is 15 mg per kg bodyweight, equivalent to 1 ml per 10 kg bodyweight to be repeated once after 48 hours.

Cattle, sheep and pigs - intramuscular use only.

Dogs and cats - subcutaneous or intramuscular use.

Shake the vial vigorously to achieve full resuspension before use.

This product does not contain an antimicrobial preservative. Swab the septum before removing each dose.

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

Maximum injection volume per injection site is 15 ml. A separate injection site should be used for each administration.

The stopper should not be punctured more than 40 times.

CONTRAINDICATIONS AND WARNINGS

- Do not administer via the intravenous or intrathecal routes
- Do not administer to rabbits, hamsters, gerbils or guinea pigs.
- Do not use in known cases of hypersensitivity to penicillins, cephalosporins or any of the excipients.
- 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.

WITHDRAWAL PERIODS

Cattle:

- Meat and offal: 39 days

- Milk: 108 hours

Pigs:

- Meat and offal: 42 days

Sheep:

- Meat and offal: 29 days

- Milk: Not authorised for use in sheep producing milk for human consumption.

PHARMACEUTICAL INFORMATION AND PRECAUTIONS

Special precautions 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.

Official, national and regional antimicrobial policies should be taken into account when the product is used.

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to amoxicillin and may decrease the effectiveness of treatment with other penicillins, due to the potential for cross-resistance.

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

Care should be taken to avoid accidental self-injection. In the 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 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 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.

Adverse reactions (frequency and seriousness):

In very rare cases, allergic reactions may occur, varying in severity from a light skin reaction such as urticaria to anaphylactic shock.

In the case of allergic reactions, treatment should be discontinued and a symptomatic treatment should be initiated.

In rare cases local irritation may occur due to the injection of amoxicillin. The frequency of this adverse reaction may be decreased by reducing the volume of injection per injection site. The irritation is typically of low intensity and recedes spontaneously and quickly.

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).

LEGAL CATEGORY

UK ONLY: POM-V

Vm No: 05150/5003

IE: POM

VPA 10990/051/001

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