

Animalcare Limited

Telephone:01904 487 687

Website:www.animalcare.co.uk

Email:office@animalcare.co.uk

Amoxycare 250mg Capsules

Species:Dogs

Therapeutic indication:Pharmaceuticals: Antimicrobials: Oral preparations: Tablets

Active ingredient:Amoxicillin Trihydrate

Product:Amoxycare 250mg Capsules

Product index:Amoxycare 250mg Capsules

Qualitative and quantitative composition

Each capsule contains:

Active Ingredient mg per capsule

Amoxicillin 250

(as Amoxicillin trihydrate)

Capsule Body:

Erythrosin (E127) 0.0011

Quinoline yellow (E104) 0.00329

Titanium dioxide (E171) 0.48311

Capsule Cap:

Erythrosin (E127) 0.549

Ferric Oxide Red (E172) 0.244

Titanium dioxide (E171) 1.1952

Ink:

Black Iron Oxide (E172)

For a full list of excipients, see pharmaceutical particulars

Pharmaceutical form

Capsule, hard.

Red and white coloured hard gelatine capsule with the logo, AMOX 250, printed in black ink.

Clinical particulars

Target species

Dogs.

Indications for use, specifying the target species

The product is indicated in the treatment and control of diseases caused by or associated with bacterial pathogens sensitive to Amoxicillin. These include the following groups of pathogens.

Pasturella spp.

Staphylococci (penicillin sensitive strains)

Streptococci

When susceptible organisms are present treatment may be effective in the following indications:

localised infections

alimentary tract infections

respiratory infections

urogenital tract infections

secondary bacterial infections

general infections

Contraindications

Not to be administered to animals known to be sensitive to beta-lactam antibiotics.

Do not treat dogs less than 10kg bodyweight.

Not to be administered to small herbivores.

Special warnings for each target species

As with all penicillins, the product may cause hypersensitivity (allergy) following ingestion. It should not be used when the dog is known to be allergic to penicillins.

As with all other penicillins, bacterial resistance to amoxicillin may occur. Thus antibiotic sensitivity testing should be considered if a clinical condition fails to respond to treatment within 5 days.

In common with many antibiotics, administration of amoxicillin may disturb the gut flora.

Special precautions for use

(i) Precautions for use in animals

For oral administration only.

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

product to animals

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 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.

Adverse reactions (frequency and seriousness)

None known.

Use during pregnancy, lactation or lay

As with all other antibiotics, the product should be used with caution during pregnancy and lactation. There is no evidence that the use of amoxicillin presents any particular hazard either to the dam or to the foetus.

Interaction with other medicinal products and other forms of interaction

Amoxicillin is unlikely to interact significantly with any of the other drugs commonly administered to dogs.

It is not recommended to administer bactericidal and bacteriostatic antibiotics concomitantly.

Amounts to be administered and administration route

Recommended dose: 10 - 20 mg/kg twice daily for seven days. This dose may be increased and/or repeated at more frequent intervals at the clinician's discretion.

To be given by the oral route only.

The dog may be dosed with the capsule or alternatively the capsule may be added to a little feed.

Overdose (symptoms, emergency procedures, antidotes) if necessary

The safety of amoxicillin is typical of that of other penicillins in that intrinsic toxicity is very low, except in animals with specific allergy to the Beta-lactams, and this seems rare.

Withdrawal period(s)

Not applicable.

Pharmacological particulars

The product contains 250 mg Amoxicillin (as Amoxicillin trihydrate PhEur) per capsule.

It is recommended for the treatment and control of diseases in dogs caused by or associated with bacterial pathogens sensitive to Amoxicillin. It is well absorbed after oral administration giving high plasma concentrations. Excretion is via both bile and urine.

Amoxicillin is a broad spectrum antibiotic of the penicillin group, which is in turn a member of the beta-lactam group.

The mode of action of beta-lactams involves interference with cell wall synthesis and are therefore more effective when the cell wall is growing. At high dose levels the penicillins have additional bactericidal effects within the bacterial cell and may affect dormant bacteria. It is well absorbed after oral administration giving high plasma concentrations. Excretion is via both bile and urine.

Amoxicillin is bactericidal against a wide range of Gram-positive and Gram-negative bacterial pathogens found in dogs including the following:

Pasturella spp., *Staphylococci* (penicillin sensitive strains), and *Streptococci*.

ATC vet code: QJ01CA04

Pharmaceutical particulars

List of excipients

Magnesium stearate

Sodium lauryl sulphate

Capsule Body:

Erythrosin (E127)

Quinoline yellow (E104)

Titanium dioxide (E171)

Gelatin

Purified water

Capsule Cap:

Erythrosin (E127)

Ferric Oxide Red (E172)

Titanium dioxide (E171)

Gelatin

Purified water

Ink:

Black Iron Oxide (E172)

Shellac

Dehydrated Alcohol

Isopropyl Alcohol

N-Butyl Alcohol

Propylene Glycol

Strong Ammonia Solution

Potassium Hydroxide

Industrial Methylated Spirit

Purified Water

Incompatibilities

None known.

Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:3 Years.

Special precautions for storage

Do not store above 25°C.

Store in a dry place.

Protect from light.

Nature and composition of immediate packaging

Polypropylene securitainer with low density polyethylene cap as pack sizes of 100, 500 or 1000 capsules.

Not all pack sizes may be marketed.

Special precautions for the disposal of unused veterinary medicinal products 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.

Marketing Authorisation Holder (if different from

distributor)

Bimeda Animal Health Limited

2 / 3 / 4 Airton Close,

Tallaght, Dublin 24,

Ireland

Marketing Authorisation Number

Vm 50146/4009

Significant changes

Date of the first authorisation or date of renewal

03 May 2000

Date of revision of the text

October 2018

Any other information

Legal category

Legal category:POM-V

GTIN

GTIN description:Amoxycare 250mg capsules

GTIN:5055037400571