

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Container label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxycare™ 250mg, hard capsules

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Amoxicillin as Amoxicillin Trihydrate

3. PHARMACEUTICAL FORM

Red and white capsules for oral administration.

4. PACKAGE SIZE

100 Capsules
500 Capsules
1000 Capsules

5. TARGET SPECIES

Dogs

6. INDICATION(S)

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: *Pasteurella* 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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

DOSAGE AND ADMINISTRATION: 10 - 20 mg/kg bodyweight twice daily for seven days.

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.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY
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SPECIAL PRECAUTIONS FOR USE:

Operator warning: 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 that 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.
4. Wash hands after use.

DRUG INTERACTIONS:

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.

USE DURING PREGNANCY OR LACTATION:

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.

CONTRA-INDICATIONS, WARNINGS etc.:

As with all penicillins the product may cause hypersensitivity (allergy) following ingestion.

Not to be administered to animals known to be sensitive to penicillin.

Not to be administered to small herbivores.

Do not treat dogs less than 10kg bodyweight.

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.

10. EXPIRY DATE

Expiry Date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Store in a dry place.
Protect from light.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MAH:

Bimeda Animal Health Limited
2 / 3 / 4 Airtton Close,
Tallaght, Dublin 24,
Ireland

Distributed By:

Animalcare Ltd., 10 Great North Way, York YO26 6RB, UK

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4009

17. MANUFACTURER’S BATCH NUMBER

Batch No:

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Amoxycare, 250mg, hard capsules:

Not applicable as all required information is on the product containers

Approved: 24 October 2018

D. Austin