

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Container label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ampicare™ 250mg, hard capsules
For the treatment and prevention of infections in dogs caused by bacteria sensitive to ampicillin.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ampicillin as Ampicillin Trihydrate

3. PHARMACEUTICAL FORM

Red and grey capsules for oral administration. Each capsule contains 250 mg ampicillin (as ampicillin trihydrate).

4. PACKAGE SIZE

100 Capsules
250 Capsules
500 Capsules

5. TARGET SPECIES

Dogs

6. INDICATION(S)

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 of less than 10 kg bodyweight.

As with all other penicillins, bacterial resistance to ampicillin may occur.

Antibiotic sensitivity testing should be considered if a clinical condition fails to respond to treatment within 3 to 5 days.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

DOSAGE AND ADMINISTRATION:

10 - 20 mg/kg twice daily. The higher dose levels are advised when treating infections due to Gram negative bacteria and in cases involving young animals.

Therapy should be repeated every 12 hours and continued for a maximum of 5 days. In severe or acute conditions, the dose levels may be increased. To be given by the oral route only. The capsules should be administered on an empty stomach.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY
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USES:

Ampicillin is a broad spectrum antibiotic active against many Gram positive and Gram negative bacteria. Ampicare can be used for the treatment and prevention of infections in dogs caused by the following bacteria provided that they are sensitive to ampicillin: *Streptococcus* spp., *Pasteurella haemolytica*, *P. multocida*, *Staphylococcus aureus* and other pathogenic staphylococci (non β lactamase producing). When susceptible organisms are present, treatment with Ampicare may be effective in the following conditions: alimentary tract infections, respiratory infections, urinary tract infections.

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.

Wash hands after use.

DRUG INTERACTIONS:

Ampicillin 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:

No studies have been carried out on pregnant animals, but the evidence provided suggests that ampicillin does not present any particular hazard either to the dam or foetus.

10. EXPIRY DATE

Expiry Date:

11. SPECIAL STORAGE CONDITIONS

PHARMACEUTICAL PRECAUTIONS:

Do not store above 25°C.

Store in a dry place.

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

DISPOSAL: 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.

POM-V

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 MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2 / 3 / 4 Airtown Close
Tallagh
Dublin 24
Ireland

Distributed By:

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

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4035

17. MANUFACTURER’S BATCH NUMBER

Batch No:

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Ampicare, 250mg, hard capsules:

Not applicable as all required information is on the product containers

Approved: 26 October 2018

D. Austin