SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ampicare, 250mg, hard capsule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient	mg per capsule
Ampicillin (as ampicillin trihydrate)	250
Capsule Body	
Erythrosine (E127)	0.952
Quinoline Yellow (E104)	0.004
Patent Blue V (E131)	0.002
Titanium Dioxide (E171)	0.368
Capsule cap	
Ferric Oxide black (E172)	0.146
Titanium Dioxide (E171)	0.488
Ink:	
Black Iron Oxide (E172)	

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsule, hard.
Red and grey coloured hard gelatine capsule with the logo, AMP 250, in black ink.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

Indicated in the treatment and control of diseases caused by or associated with bacterial pathogens sensitive to ampicillin. These include the following groups of pathogens:

Streptococcus spp., *Pasturella haemolitica, P. multocida, Staphylococcus aureus* and other pathogenic staphylococci.

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

alimentary tract infections
respiratory infections
urinary tract infections

4.3 Contraindications

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.

4.4 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 ampicillin may occur. Thus antibiotic sensitivity testing should be considered if a clinical condition fails to respond to treatment within 3 to 5 days.

4.5 Special precautions for use

i. Special 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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interaction

Ampicillin is unlikely to interact significantly with any other drugs commonly administered to dogs. It is not recommended to administer bactericidal and bacteriostatic antibiotics concomitantly.

4.9 Amounts to be administered and administration route

Recommended dose: 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.

4.10 Overdose (symptoms, emergency procedures, antidotes) if necessary

The safety of ampicillin is typical of that of other penicillins in that intrinsic toxicity is very low, except in animals with specific allergy to the beta-lactams.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, beta-lactam antibacterials, penicillins, penicillins with extended spectrum

ACTVet code: QJ01CA01

The product contains ampicillin (as the trihydrate) 250 mg per capsule.

It is recommended for the treatment and control of diseases in dogs caused by or associated with bacterial pathogens sensitive to ampicillin.

Ampicillin is a broad spectrum antibiotic of the penicillin group, which is in turn a member of the beta-lactam group. It is well absorbed after oral administration but bioavailability is reduced by food in the stomach.

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.

Ampicillin is bactericidal against a wide range of Gram-positive and Gram-negative bacterial pathogens found in dogs including the following, provided that they are sensitive to ampicillin:

Streptococcus spp., *Pasturella haemolytica, P. multocida, Staphylococcus aureus* and other pathogenic staphylococci (non β lactamase producing).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate

Capsule Body:
Erythrosin (E127)
Quinoline Yellow (E104)
Patent Blue V (E131)
Titanium dioxide (E171)
Gelatin
Purified water

Capsule Cap:
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

6.2 Incompatibilities

None known.

6.3 Shelf Life

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

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Polypropylene securitainer with low density polyethylene cap.
Pack sizes of 100, 250 and 500 capsules per container.
Not all pack sizes may be marketed.

6.6 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.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 50146/4035

9. DATE OF THE FIRST AUTHORISATION

24 March 2000

10. DATE OF REVISION OF THE TEXT

October 2018

Approved: 26 October 2018

D. Austin