Summary of Product Characteristics

1. NAME OF VETERINARY MEDICINAL PRODUCT

Amoxycare, 250mg, hard capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Active Ingredient	mg per capsule
Amoxicillin (as Amoxicillin trihydrate)	250
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 section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 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 Amoxycillin. 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

4.3 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.

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 amoxycillin 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 amoxycillin may disturb the gut flora.

4.5 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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 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 amoxycillin presents any particular hazard either to the dam or to the foetus.

4.8 Interaction with other medicinal products and other forms of interaction

Amoxycillin 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.

4.9 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.

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

The safety of amoxycillin 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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

The product contains 250 mg Amoxycillin (as Amoxycillin 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 Amoxycillin. It is well absorbed after oral administration giving high plasma concentrations. Excretion is via both bile and urine.

Amoxycillin 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.

Amoxycillin 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

6. PHARMACEUTICAL PARTICULARS

6.1 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

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.
Protect from light.

6.5 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.

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

Cross Vetpharm Group Ltd
Broomhill Road, Tallaght,
Dublin 24

8. MARKETING AUTHORISATION NUMBER

Vm No: 12597/4036

9. DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

3rd May 2000/ before 3rd May 2005

10. DATE OF REVISION OF THE TEXT

February 2008

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