SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxycare Palatable Drops Powder for Oral Suspension 50mg/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance: Each bottle contains the equivalent of 750 mg amoxicillin (as Amoxicillin Trihydrate Ph.Eur.) and when reconstituted with 12 ml water gives a 15 ml suspension containing amoxicillin at a concentration of 50 mg/ml.

Excipients:

Erythrosine E127 2.34 mg per bottle

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder for oral suspension
A pale red powder

4. CLINICAL PARTICULARS

4.1 Target species

Dogs
Cats

4.2 Indications for use, specifying the target species

For the control of infections in dogs and cats caused by susceptible organisms, including infections of the alimentary tract, respiratory tract and urogenital tract, eye and ear infections, and skin and wound infections. *In vitro*, amoxicillin is effective against a wide range of Gram-positive and Gram-negative bacteria, including:

Bacillus cereus
Bordetella bronchiseptica
Corynebacterium spp
Citrobacter freundii
Chromobacter spp
Escherichia coli
Flavobacter spp
Pasteurella spp (including *P. multocida*)
Proteus mirabilis

Salmonella spp
Staphylococci (penicillin sensitive stains)
Streptococci

4.3 Contraindications

Not to be used in animals known to be hypersensitive to penicillin.

Not to be used orally or parenterally in rabbits, guinea pigs, hamsters or gerbils.

Caution is advised when used in any other small herbivores

4.4 Special Warnings for each target species

No special warnings.

4.5 Special precautions for use

Special precautions for use in animals

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local epidemiological information.

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)

No known undesirable effects

4.7 Use during pregnancy, lactation or lay

No known contraindications.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Reconstitution: Add 12 ml water to the powder and shake vigorously. This will make 15 ml of the suspension, containing amoxicillin at a concentration of 50 mg/ml.
Administration and Dosage: Recommended dosage rate is 10 mg/kg bodyweight amoxicillin twice daily for up to 7 days. The drops are given orally using a graduated pipette provided. The dosage rate of 10 mg/kg is achieved by administering 1 ml of reconstituted product per 5 kg bodyweight.

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

Shake well before use

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

No treatment specified.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibiotic

ATC Vet Code: QJ01CA04

5.1 Pharmacodynamic properties

Amoxicillin is a broad-spectrum semi-synthetic penicillin. Amoxicillin predominately inhibits cell wall synthesis in susceptible bacteria. Amoxicillin has a mode of action which directly and irreversibly disrupts cell wall peptidoglycan.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Erythrosine (E127)
Trusil Strawberry Select Flavour H9922
Lactose Monohydrate

6.2 Incompatibilities

None.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale : 2 years.
Shelf-life after dilution or reconstitution according to directions : 28 days.

6.4 Special precautions for storage

Do not store above 25ºC.
The reconstituted product should not be stored above 25ºC.
Any reconstituted product remaining 7 days after preparation should be discarded.

6.5 Nature and composition of immediate packaging

A white polyethylene/polypropylene bottle with a white, wadded polypropylene screw cap containing 7.5g of pale red powder.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

Norbrook Laboratories Limited
Station Works
Newry
Co. Down, BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER(S)

Vm: 02000/4157

9. DATE OF FIRST AUTHORISATION

9th February 1998

10. DATE OF REVISION OF THE TEXT

December 2008