Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Betamox Palatable Drops Powder for Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients:
Erythrosine (E127) 0.312 mg.

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

Amoxycillin is a broad spectrum semi-synthetic penicillin bactericidal in action. In vitro it is effective against a wide range of Gram-positive and Gram-negative bacteria found in dogs and cats including: *Bacillus cereus, Bordetella bronchiseptica, Corynebacterium spp, Citrobacter freundii*, *Chromobacter spp, Flavobacter spp, Pasteurella spp* (including P. *multocida), Salmonella* spp, Staphylococci (penicillin sensitive strains), Streptococci.
Some effect has been observed against *Escherichia coli.* Betamox Palatable Drops are suitable for the control of infections caused by susceptible organisms including: infections of the alimentary tract, respiratory tract and urogenital tract, eye and ear infections and skin and wound infections

4.3 Contraindications

Betamox Palatable Drops should not be given to penicillin sensitive animals.

As with other penicillins, amoxycillin should not be used orally or parenterally in rabbits, guinea pigs, hamsters or gerbils.

Caution is advised when used in any other very small herbivores.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

None.

Special Precautions to be taken by the Person Administering the Medicinal Product to Animals

Penicillin and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross sensitivity to cephalosporins and vice versa. Allergic reaction to these substances can 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 and eyes or difficulty with breathing are more serious symptoms and require urgent medical attention

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Betamox Palatable Drops can be safely administered during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

Shake well before use.

Administer orally using the graduated pipette provided, at a rate of 10 mg/kg bodyweight, twice daily for up to seven days. The dosage rate of 10 mg/kg is achieved by administering 1 ml of reconstituted product per 5 kg bodyweight.

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

Not applicable

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use; Beta-Lactam antibacterials; Amoxicillin.
ATCvet code: QJ01CA04

5.1 Pharmacodynamic properties

Amoxycillin predominately inhibits cell wall synthesis in susceptible bacteria. Amoxycillin has a unique mode of action which directly and irreversibly disrupts existing cell wall peptidoglycan rather than newly forming peptidoglycan of the divisory septal wall as with other members of the penicillin family.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Erythrosine E127 Trasil strawberry select flavourLactose

6.2 Major incompatibilities

Not applicable.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: 7 days.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

A 40 ml polyethylene bottle sealed with a white cap.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/020/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1987
Date of last renewal: 30 September 2007

10 DATE OF REVISION OF THE TEXT

January 2019