

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Betamox 40 mg Palatable Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Amoxicillin Trihydrate 45.92 mg which is equivalent to 40.00 mg amoxicillin.

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Tablet. Off-white circular tablets scored on one face.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs, Cats.

4.2 Indications for use, specifying the target species

For the treatment of infections caused by a wide range of Gram-positive and Gram-negative pathogenic bacteria including:

Bacillus cereus

Bordetella bronchiseptica

Corynebacterium spp.

Chromobacter spp

Citrobacter freundii

Flavobacter spp.

Proteus mirabilis

Pasteurella spp., including Pasteurella multocoda

Salmonella spp.

Staphylococci (penicillin sensitive strains)

Streptococci

Effect has been observed against some strains of *Escherichia coli*.

4.3 Contraindications

Betamox 40 mg Palatable Tablets should not be given to penicillin sensitive animals.

As with other penicillins, amoxicillin 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

Hypersensitivity reactions may occur to the active ingredient in treated patients.

4.5 Special precautions for use

Special precautions for use in animals

None.

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

Penicillins 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 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 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 40 mg Palatable Tablets may be safely administered during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

The recommended dose rate is 10 mg/kg bodyweight (one tablet per 4 kg bodyweight) twice daily for 7 days.

Tablets are given orally by hand or crushed in food.

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

ATCvet Code: QJ01CA04

5.1 Pharmacodynamic properties

Amoxicillin predominately inhibits cell wall synthesis in susceptible bacteria. Amoxicillin 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

Microcrystalline cellulose
Lactose
Sodium starch glycollate
Povidone
Yeast extract, spray dried
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Store in a dry place below 25°C.

6.5 Nature and composition of immediate packaging

Polypropylene plastic containers of the following sizes:

100 x Betamox 40 mg Tablets
500 x Betamox 40 mg Tablets

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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 Ltd.,
Station Works,
Newry,
Co. Down,
BT35 6JP,
Northern Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10999/15/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2002 / 30th September 2007

10 DATE OF REVISION OF THE TEXT