SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Betamox 40mg Palatable Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains :

Active Substance:

Amoxicillin	40 mg
(as Amoxicillin Trihydrate)	45.92 mg

Excipients:
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 use in the treatment of bacterial infections of the alimentary, respiratory and urogenital tracts and in the eye, ear, skin and wound infections caused by susceptible organisms. *In vitro*, amoxicillin is effective against a range of Gram-positive and Gram-negative bacteria, including:

Bacillus cereus
Bordetella bronchiseptica
Corynebacterium spp
Chromobacter spp
Citrobacter freundii
Escherichia coli
Flavobacter spp
Proteus mirabilis
Pasteurella spp *including Pasteurella multocida*
Salmonella spp
Staphylococci (penicillin sensitive strains)
Streptococci

4.3 Contraindications

Do not use in known cases of hypersensitivity to amoxicillin.
Not for administration to rabbits, guinea pigs, hamsters or gerbils.
Caution is advised when used in 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
None

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 contraindication exists for use of 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 amoxicillin per kg bodyweight (one tablet per 4kg bodyweight) twice daily for 7 days.

Tablets are given orally by hand or crushed in food.

Any remaining medicated feed should be disposed of at the end of the day.

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

Penicillins have a remarkably good safety record and overdose is highly unlikely.

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. Amoxicillin is well absorbed following oral administration.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cellulose Microcrystalline
Lactose Monohydrate
Sodium Starch Glycollate
Povidone K17
Yeast Dried (spray dried)
Magnesium Stearate

6.2 Incompatibilities

None known

6.3 Shelf-life

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

6.4 Special precautions for storage

Do not store above 25ºC. Store in a dry place.

6.5 Nature and composition of immediate packaging

Betamox 40mg Palatable Tablets are supplied in white opaque high density polypropylene tubs with white opaque tamper evident, push-fit low density polyethylene caps of the following sizes:

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

Not all pack sizes may be marketed

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 02000/4087

9. DATE OF FIRST AUTHORISATION

22nd September 1987

10. DATE OF REVISION OF THE TEXT

July 2008