

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxycare 200mg Tablets.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Each tablet contains Amoxicillin (as Amoxicillin Trihydrate) 200 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 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

Citrobacter freundii

Chromobacter spp

Escherichia coli

Flavobacter spp

Proteus mirabilis

Pasteurella spp including *Pasteurella multocida*

Salmonella spp

Staphylococci (penicillin sensitive strains)

Streptococci

4.3 Contraindications

Amoxycare 200mg 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 other very 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

Penicillin's 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 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 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

No known contraindication exists for the use of Amoxycare 200mg Tablets 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 dosage rate is 10 mg amoxicillin/kg bodyweight (one tablet per 20 kg bodyweight) twice daily for 7 days. Tablets are given orally, by hand or crushed in food. To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

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 wide safety margin and adverse effects are unlikely even in accidental overdose.

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 predominantly 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

Microcrystalline Cellulose
Lactose Monohydrate
Sodium Starch Glycollate
Povidone K17
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

Do not store above 25°C. Store in a dry place

6.5 Nature and composition of immediate packaging

Amoxycare 200mg Tablets are supplied in white, polypropylene tubs with white, low-density polyethylene closures of the following sizes:

100 tablets
250 tablets
500 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: 02000/4143

9. DATE OF FIRST AUTHORISATION

29th December 1997

10. DATE OF REVISION OF THE TEXT

December 2008