

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

100/250/500 TABLET - TUB

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxycare 200mg Tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

200 mg amoxicillin as amoxicillin trihydrate

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

100/250/500 Tablets

5. TARGET SPECIES

Dogs and Cats

6. INDICATION(S)

See package leaflet

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration to dogs and cats

The recommended dose is 10 mg amoxicillin per kg bodyweight twice daily for seven days, e.g.

DOGS per 20 kg: 1 tablet twice daily for 7 days.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Not to be administered to animals sensitive to penicillin. Not to be used in rabbits, guinea pigs, hamsters or gerbils. Caution is advised in its use in any other very small herbivores.

Wash hands after use. Penicillins/cephalosporins may occasionally cause severe allergic reactions. See package leaflet for user warning.

10. EXPIRY DATE

Exp.: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For Animal Treatment Only.

POM-V

To be supplied only on Veterinary prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

Station Works

Newry

Co. Down, BT35 6JP

Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm: 02000/4143

ManA 2000

17. MANUFACTURER'S BATCH NUMBER

Bn.:

D.O.M.:

Further Information:

See package leaflet.

Distributed by:

Animalcare Ltd

10 Great North Way

York

YO26 6RB

Amoxycare is a trademark of Animalcare Ltd

PACKAGE LEAFLET FOR: AMOXYCARE 200MG TABLETS

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Norbrook Laboratories Limited

Station Works

Newry

Co. Down, BT35 6JP

Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxycare 200mg Tablets

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Amoxycare 200mg Tablets are presented as off-white circular tablets scored on one face. The tablets contain 200 mg amoxicillin as amoxicillin trihydrate in a highly palatable base. Chemically amoxicillin is 6(D(-)- α -amino-p-hydroxy-phenylacetamido) penicillanic acid.

4. INDICATION(S)

Amoxicillin 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 which include: *Bacillus cereus*, *Bordetella bronchiseptica*, *Corynebacterium* spp, *Citrobacter freundii*, *Chromobacter* spp, *Escherichia coli*, *Flavobacter* spp, *Proteus mirabilis*, *Pasteurella* spp including *P. multocida*, *Salmonella* spp, *staphylococci* (penicillin-sensitive strains) and *streptococci*.

Amoxycare 200mg Tablets are suitable 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.

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.

5. 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 any other very small herbivores.

6. ADVERSE REACTIONS

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs and Cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Administer orally by hand.

The recommended dose rate is 10 mg amoxicillin/kg bodyweight twice daily for seven days.

The following is intended as a guide:

DOGS per 10kg: $\frac{1}{2}$ x 200mg tablet twice daily for 7 days

or per 20 kg: 1 x 200 mg tablet twice daily for 7 days

9. ADVICE ON CORRECT ADMINISTRATION

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing. As high blood levels are achieved immediately after oral dosing parenteral antibiotic treatment may not be necessary. Amoxycare 200mg Tablets are often accepted from the hand, however for the treatment of fastidious animals the tablets may be crushed and added to a little food. Any remaining medicated feed should be disposed of at the end of the day.

10. WITHDRAWAL PERIOD(S)

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Store in a dry place.

Do not store above 25°C.

Keep out of reach of children.

12. SPECIAL WARNING(S)

Penicillins and cephalosporins may cause hypersensitivity 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2013

<15. OTHER INFORMATION>

POM – V To be supplied only on veterinary prescription

Package Quantities:

Amoxycare 200mg_Tablets are supplied in plastic tubs of 100 tablets, 250 tablets and 500 tablets.

Marketing Authorisation No:

Vm 02000/4143

ManA 2000

Distributed By:

Animalcare Ltd

10 Great North Way

York

YO26 6RB

FOR ANIMAL TREATMENT ONLY

LOGO

Approved: 31/01/2018

A handwritten signature in black ink, appearing to read 'J. King', positioned below the approval date.