PARTICULARS TO APPEAR ON THE OUTER PACKAGE

100/500/1000 TABLET – TUB LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxycare 40mg Tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:

40mg amoxicillin as amoxicillin trihydrate

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

100/500/1000 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 10mg amoxicillin per kg bodyweight twice daily for seven days, e.g.

CATS per 4kg: 1 tablet twice daily for 7 days.

DOGS per 8kg: 2 tablets 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.

Penicillins/cephalosporins may occasionally cause severe allergic reactions. Wash hands after use. 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 25ºC.

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 No. 02000/4142

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

PACKAGE LEAFLET FOR: AMOXYCARE 40MG 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 40mg Tablets

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

Amoxycare 40 mg Tablets are prepared as off-white circular tablets scored on one face. The tablets contain 40 mg amoxicillin as amoxicillin trihydrate in a highly palatable base. Chemically, amoxicillin is 6-[D(-)-α-amino-p-hydroxyphenylacetamido] 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 40mg Tablets are suitable for use in dogs and cats 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.

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 40mg 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 is 10mg Amoxicillin/kg bodyweight twice daily for seven days.

The following is intended as a guide:

CATS per 4kg: 1 x 40mg tablet twice daily for 7 days

DOGS per 8kg: 2 x 40mg tablets 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 40mg 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 discarded 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)

Operator Warning - Penicillin/Cephalosporin Sensitivity:

Penicillins and cephalosporins may cause sensitisation following injection, inhalation, ingestion or skin contact. Sensitivity to penicillins may lead to cross sensitivity to cephalosporins and vice versa. Allergic reactions to these substances are occasionally 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 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>

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FOR ANIMAL TREATMENT ONLY

Approved: 31/01/2018