PARTICULARS TO APPEAR ON THE OUTER PACKAGE {LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxycare Palatable Drops Powder for Oral Suspension 50mg/ml

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Amoxicillin trihydrate equivalent to 750 mg amoxicillin. The powder should be reconstituted with 12 ml water to give a 15 ml suspension containing amoxicillin at a concentration of 50 mg/ml

3. PHARMACEUTICAL FORM

Palatable Drops

4. PACKAGE SIZE

15ml

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: 1 ml per 5 kg bodyweight twice daily for up to seven days.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Shake well before use.

Do not administer 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 small herbivores.

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

Do not store above 25ºC. The reconstituted product should not be stored above 25ºC; any reconstituted product remaining 7 days after preparation should be discarded.

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

Dispose of used packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

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 reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

16. MARKETING AUTHORISATION NUMBER(S)

Vm: 02000/4157

Man A 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

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxycare Palatable Drops Powder for Oral Suspension 50mg/ml

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Amoxicillin trihydrate equivalent to 750 mg amoxicillin. The powder should be reconstituted with 12 ml water to give a 15 ml suspension containing amoxicillin at a concentration of 50 mg/ml

3. PHARMACEUTICAL FORM

Palatable Drops

4. PACKAGE SIZE

15ml

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: 1 ml per 5 kg bodyweight twice daily for up to seven days.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Shake well before use.

Do not administer 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 small herbivores.

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

Do not store above 25ºC. The reconstituted product should not be stored above 25ºC; any reconstituted product remaining 7 days after preparation should be discarded.

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

Dispose of used packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

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 reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

16. MARKETING AUTHORISATION NUMBER(S)

Vm: 02000/4157

Man A 2000

17. MANUFACTURER'S BATCH NUMBER

Bn.:

D.O.M.:

Further Information: See package leaflet

Once re-constituted, use by: __/__/__

Distributed by:
Animalcare Ltd
10 Great North Way
York
YO26 6RB

PACKAGE LEAFLET FOR: Amoxycare Palatable Drops Powder for Oral Suspension 50mg/ml

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 Palatable Drops Powder for Oral Suspension 50mg/ml

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

Amoxycare Palatable Drops are presented as a pale red powder containing amoxicillin trihydrate equivalent to 750mg amoxicillin.

The powder should be reconstituted with 12 ml water to give a 15 ml suspension containing amoxicillin at a concentration of 50 mg/ml.

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 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) and *Streptococci*.

Amoxycare Palatable Drops are suitable for the control of infections only 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 Palatable Drops 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, using the graduated pipette provided, at a rate of 10 mg/kg bodyweight, twice daily for up to seven days.

The dosage rate of 10 mg/kg is achieved by administering 1 ml of reconstituted product per 5 kg bodyweight.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use.

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

10. WITHDRAWAL PERIOD(S)

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC.

The reconstituted product should not be stored above 25ºC; any reconstituted product remaining 7 days after preparation should be discarded.

After the product is re-constituted, using the in-use shelf-life which is specified on this package leaflet, the date on which any re-constituted product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the carton.

Keep out of the reach of children**.**

12. SPECIAL WARNING(S)

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 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 used packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2013

15. OTHER INFORMATION

Legal Category:

POM-V To be supplied only on Veterinary prescription

Package Quantities:
Amoxycare Palatable Drops are packaged in bottles containing Amoxicillin Trihydrate equivalent to 750 mg amoxicillin. To enable convenient and accurate dosing a graduated pipette is provided with each pack.

Further Information:
Nil

Marketing authorisation No:
Vm 02000/4157
ManA 2000
Distributed by:
Animalcare Ltd
10 Great North Way

York
YO26 6RB

FOR ANIMAL TREATMENT ONLY LOGO

Approved: 25/07/2017