

**PARTICULARS TO APPEAR ON <THE IMMEDIATE PACKAGE> 100/200**  
**TABLET TUB**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Betamox 200 mg Palatable Tablets

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each tablet contains:  
200 mg amoxicillin (as Amoxicillin Trihydrate 229.70 mg).

**3. PHARMACEUTICAL FORM**

Tablets for oral administration

**4. PACKAGE SIZE**

100/250 Tablets

**5. TARGET SPECIES**

Dogs and Cats

**6. INDICATION(S)**

For oral administration to dogs and cats

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

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.

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

Further Information: See package leaflet.

**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 [Distribution category]**

FOR ANIMAL TREATMENT ONLY

POM-V
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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**

Norbrook Laboratories Limited,  
Station Works, Newry, Co. Down, BT35 6JP,  
Northern Ireland.

#### **16. MARKETING AUTHORISATION NUMBER(S)**

Vm: 02000/4103

ManA 2000

#### **17. MANUFACTURER’S BATCH NUMBER**

B.N.:

D.O.M:

## **PACKAGE LEAFLET FOR:**

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

Norbrook Laboratories Limited  
Newry,  
Co. Down,  
BT35 6JP

### **2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Betamox 200 mg Palatable Tablets

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

Betamox 200 mg Palatable Tablets are presented as off-white circular tablets scored on one face. The tablets contain 200 mg amoxicillin (as Amoxicillin Trihydrate 229.7 mg) in a highly palatable base. Chemically Amoxicillin is 6(D-)- $\alpha$ -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.

Betamox 200 mg Palatable 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.

### **5. CONTRAINDICATIONS**

Betamox 200 mg Palatable Tablets should not be given to penicillin sensitive animals.

As with other penicillins, amoxycillin 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.

*Operator warning - penicillin/cephalosporin sensitivity:* 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.

## **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 10 kg:  $\frac{1}{2}$  x 200 mg 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**

As high blood levels are achieved immediately after oral dosing parenteral antibiotic treatment may not be necessary. Betamox 200 mg Palatable 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 the reach and sight of children.

## **12. SPECIAL WARNING(S)**

None

## **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**

August 2012

## **15. OTHER INFORMATION**

Betamox 200 mg Palatable Tablets are supplied in white opaque high density polypropylene tubs with white opaque push-fit low density polyethylene caps of the following sizes:

100 x Betamox 200 mg Tablets and 250 x Betamox 200 mg Tablets

Not all pack sizes may be marketed.

### **Marketing Authorisation No:**

Vm 02000/4103

ManA 2000

### **Manufactured by:**

Norbrook Laboratories Limited

Newry, Co. Down, BT35 6JP

### **Distributed By:**

Norbrook Laboratories (GB) Limited

1 Saxon Way East

Oakley Hay Industrial Estate

Corby

Northamptonshire

NN18 9EX

United Kingdom

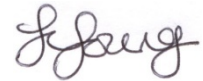
### **Legal Category:**

POM-V

To be supplied only on veterinary prescription

FOR ANIMAL TREATMENT ONLY

**Approved: 23/08/2017**

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