# ANNEX III

# LABELLING AND PACKAGE LEAFLET

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**50 ml/100 ml/250 ml/500 ml**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Betamox LA 150 mg/ml Suspension for Injection

## 2. STATEMENT OF ACTIVE SUBSTANCES

Betamox LA is an off white oily suspension containing 150 mg/ml amoxicillin as Amoxicillin Trihydrate (17.21 % w/v), 0.08 mg/ml (0.008% w/v) butylated hydroxytoluene and 0.08 mg/ml (0.008% w/v) butylated hydroxyanisole as antioxidants.
Chemically, Amoxicillin is 6[D(-) - ∝- amino-p-hydroxy-phenylacetamido] penicillanic acid.

## 3. PHARMACEUTICAL FORM

Suspension for Injection

## 4. PACKAGE SIZE

50 ml/100 ml/250 ml/500 ml

## 5. TARGET SPECIES

Cattle, Sheep, Pigs, Dogs and Cats

## 6. INDICATION(S)

Amoxicillin is a broad-spectrum semi-synthetic penicillin bactericidal in action for use in cattle, pigs, sheep, dogs and cats. *In vitro* it is effective against a wide range of Gram-positive and Gram-negative bacteria which include: *Escherichia coli, Klebsiella pneumoniae, Proteus* species*, Salmonella* species*,* Staphylococci and Streptococci*.*
Betamox LA is suitable for the control of infections, due to susceptible microorganisms, in cattle, sheep, pigs, dogs and cats where a single injection giving prolonged activity is required. It may also protect from secondary bacterial invasion by sensitive organisms in cases where bacteria are not the initial cause of the disease.

Indications include infections of:
(a) Alimentary tract,
(b) Respiratory tract,
(c) Skin and soft tissue,
(d) Urogenital tract and,
(e) In prevention of post-operative infection (treat before surgery).

**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.**

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

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.
Swab the septum before removing each dose. Use a dry, sterile needle and syringe.
Cattle, Sheep and Pigs: By intramuscular injection only.
Dogs and Cats: By subcutaneous or intramuscular injection.
The recommended dosage rate is 15 mg per kg bodyweight, repeatable if necessary after 48 hours. Massage the injection site. A separate injection site should be used for each administration.

| ANIMAL | WEIGHT (kg) | DOSAGE VOLUME (ml) |
|---|---|---|
| Cattle | 450 kg | 45.0 ml |
| Sheep | 65 kg | 6.5 ml |
| Pig | 150 kg | 15.0 ml |
| Dog | 20 kg | 2.0 ml |
| Cat | 5 kg | 0.5 ml |

Dose volume is equivalent to 1 ml per 10 kg bodyweight.
If dose volume exceeds 15 ml in cattle and 4 ml in sheep and pigs, it should be divided and injected into two or more sites.
As with other injectable preparations, normal aseptic precautions should be observed. (Use dry syringe for extraction of suspension to avoid hydrolysis of Amoxicillin).
An appropriate graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

## 8. WITHDRAWAL PERIOD(S)

Cattle:
Meat and offal: 39 days
Milk: 108 hours (4.5 days)

Pigs:
Meat and offal: 42 days

Sheep:
Meat and offal: 29 days
Milk: Not authorised for use in sheep producing milk for human consumption.

## 9. SPECIAL WARNING(S), IF NECESSARY

Warning - Penicillin/Cephalosporin Sensitivity
Care should be taken to avoid accidental self-injection. In the case of accidental self-injection, seek medical advice immediately.
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 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.

## 10. EXPIRY DATE

D.O.M.:
Exp.:

## 11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.
Protect from light.
Keep out of the sight and reach of children.
Shake the vial before use.
Following withdrawal of the first dose, use the product within 28 days.
Discard unused material.
This product does not contain an antimicrobial preservative.
When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this package leaflet, the date on which any product remaining should be discarded should be worked out. This discard date should be written in the space provided.

## 12. SPECIAL 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

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

## 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
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

**Manufacturer:**
Norbrook Laboratories Limited
Newry
Co. Down
Northern Ireland

**Distributed by:**
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
BT35 6QQ
Co. Down
Northern Ireland

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4070

## 17. MANUFACTURER'S BATCH NUMBER

B.N.:

**PARTICULARS TO APPEAR ON THE IMMEDIATE LABEL**

**50 ml/100 ml/250 ml/500 ml**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Betamox LA 150 mg/ml Suspension for Injection

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: Amoxicillin (as Amoxicillin Trihydrate 17.21% w/v) 150 mg, 0.08 mg (0.008% w/v) butylated hydroxytoluene and 0.08 mg (0.008% w/v) butylated hydroxyanisole as antioxidants.

## 3. PHARMACEUTICAL FORM

Suspension for Injection

## 4. PACKAGE SIZE

50 ml/100 ml/250 ml/500 ml

## 5. TARGET SPECIES

Cattle, Sheep, Pigs, Dogs and Cats

## 6. INDICATION(S)

Read the package leaflet before use.

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

Cattle, Sheep and Pigs: By intramuscular injection only.
Dogs and Cats: By subcutaneous or intramuscular injection.

Dose volume is equivalent to 1 ml per 10 kg body weight. If dose volume exceeds 15 ml in cattle and 4 ml in sheep and pigs, it should be divided and injection into two or more sites.

15 mg/kg bodyweight (equivalent to 1 ml per 10 kg bodyweight), repeatable if necessary after 48 hours. Massage the injection site. A separate injection site should be used for each administration.

**Suggested Dosage:**

CATTLE: 450 kg - 45.0 ml
SHEEP: 65 kg - 6.5 ml
PIGS: 150 kg - 15.0 ml

DOGS: 20 kg - 2.0 ml
CATS: 5 kg - 0.5 ml

## 8. WITHDRAWAL PERIOD(S)

Cattle:
Meat and offal: 39 days
Milk: 108 hours (4.5 days)

Pigs:
Meat and offal: 42 days

Sheep:
Meat and offal: 29 days
Milk: Not authorised for use in sheep producing milk for human consumption.

## 9. SPECIAL WARNING(S), IF NECESSARY

Occasional local reaction may occur with use of Betamox LA.
Penicillin/cephalosporin may occasionally cause severe allergic reactions. See package leaflet for operator warning.
Not effective against beta-lactamase producing organisms.
Amoxicillin, like other Penicillins, should not be administered orally or parenterally in rabbits, hamsters, gerbils and guinea pigs.
Not suitable for intravenous or intrathecal administration.
Swab the septum before removing each dose. Use a dry, sterile needle and syringe.
**Further Information:** See package leaflet.

## 10. EXPIRY DATE

EXP: dd/mm/yy
Date of first broaching: ___/___/___
Date to discard: ___/___/___

## 11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC. Protect from light.
Shake the vial before use.
Following withdrawal of the first dose use the product within 28 days.
Discard unused material.
This product does not contain an antimicrobial preservative.

## 12. SPECIAL 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
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

**Manufacturer:**
Norbrook Laboratories Limited
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**Distributed by:**
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
BT35 6QQ
Co. Down
Northern Ireland

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4070

## 17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET:

## Betamox LA 150 mg/ml Suspension for Injection

## 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
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

**Manufactured by:**
Norbrook Laboratories Limited
Newry
Co. Down
Northern Ireland

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Betamox LA 150 mg/ml Suspension for Injection

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

Betamox LA is an off-white oily suspension containing 150 mg/ml amoxicillin as Amoxicillin Trihydrate (17.21%w/v), 0.08 mg/ml (0.008%w/v) butylated hydroxytoluene and 0.08 mg/ml (0.008%w/v) butylated hydroxyanisole as antioxidants.
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 for use in cattle, pigs, sheep, dogs and cats. *In vitro* it is effective against a wide range of Gram-positive and Gram-negative bacteria which include: *Escherichia coli, Klebsiella pneumoniae, Proteus* species*, Salmonella* species*,* Staphylococci and Streptococci*.*
Betamox LA is suitable for the control of infections, due to susceptible microorganisms, in cattle, sheep, pigs, dogs and cats where a single injection giving prolonged activity is required. It may also protect from secondary bacterial invasion by sensitive organisms in cases where bacteria are not the initial cause of the disease.
Indications include infections of:
(a) Alimentary tract,
(b) Respiratory tract,
(c) Skin and soft tissue,
(d) Urogenital tract and,
(e) In prevention of post-operative infection (treat before surgery).

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

Suspension is not suitable for intravenous or intrathecal administration.
Not effective against beta-lactamase producing organisms.
Amoxicillin, like other penicillins, should not be administered orally or parenterally in rabbits, hamsters, gerbils and guinea pigs.

## 6. ADVERSE REACTIONS

In rare cases, hypersensitivity reactions such as urticaria anaphylaxis shock can occur after use. In the case of allergic reactions, treatment should be discontinued and a symptomatic treatment should be initiated. In very rare cases, local tissue reactions such as swelling and pruritus may result from the use of amoxicillin.

The frequency of adverse reactions is defined using the following convention:
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Cattle, Sheep, Pigs, Dogs and Cats

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

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing or overdosing.
Swab the septum before removing each dose. Use a dry, sterile needle and syringe.

Cattle, Sheep and Pigs: By intramuscular injection only.
Dogs and Cats: By subcutaneous or intramuscular injection.

The recommended dosage rate is 15 mg per kg bodyweight, repeatable if necessary after 48 hours. Massage the injection site. A separate injection site should be used for each administration.

| ANIMAL | WEIGHT (kg) | DOSAGE VOLUME (ml) |
|---|---|---|
| Cattle | 450 kg | 45.0 ml |
| Sheep | 65 kg | 6.5 ml |
| Pig | 150 kg | 15.0 ml |
| Dog | 20 kg | 2.0 ml |
| Cat | 5 kg | 0.5 ml |

Dose volume is equivalent to 1 ml per 10 kg bodyweight.

If dose volume exceeds 15 ml in cattle and 4 ml in sheep and pigs, it should be divided and injected into two or more sites.
As with other injectable preparations, normal aseptic precautions should be observed. (Use dry syringe for extraction of suspension to avoid hydrolysis of Amoxicillin).

If no distinct clinical response is seen after the second treatment, a check of the diagnosis and eventually a change of treatment are required.

## 9. ADVICE ON CORRECT ADMINISTRATION

An appropriate graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

## 10. WITHDRAWAL PERIOD(S)

Cattle:
Meat and offal: 39 days
Milk: 108 hours (4.5 days)

Pigs:
Meat and offal: 42 days

Sheep:
Meat and offal: 29 days
Milk: Not authorised for use in sheep producing milk for human consumption.

## 11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC.
Protect from light.
Keep out of the sight and reach of children.
Shake the vial before use
Following withdrawal of the first dose, use the product within 28 days. Discard unused material. This product does not contain an antimicrobial preservative.
When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this package leaflet, the date on which any product remaining should be discarded should be worked out. This discard date should be written in the space provided.

## 12. SPECIAL WARNING(S)

Operator Warning - Penicillin/Cephalosporin Sensitivity
Care should be taken to avoid accidental self-injection. In the case of accidental self-injection, seek medical advice immediately.
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 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 or containers in accordance with guidance from your local waste regulation authority.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

## 15. OTHER INFORMATION

Due to its wide distribution, after absorption, high levels of Amoxicillin are found in kidney, urine, liver and bile.
Also important is the rapid bactericidal action.
Due to its mode of action Amoxicillin prevents recrudescence of respiratory infections.
The absence of toxicity, shared with other penicillins, is also apparent.
Animals with functional rumens should only be treated parenterally.

**PACKAGE QUANTITIES:**
Multidose glass vials of 50 ml and 100 ml, and plastic vials of 50 ml, 100 ml, 250 ml and 500ml.

Not all package sizes may be marketed.

**MARKETING AUTHORISATION NUMBER:**
Vm 02000/4070
ManA 2000

POM-V To be supplied only on veterinary prescription.

FOR ANIMAL TREATMENT ONLY

**Distributed by:**
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Northern Ireland

Approved 28 October 2022