PARTICULARS TO APPEAR ON BOTTLE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Betamox 150 mg/ml Suspension for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

5. TARGET SPECIES

Cattle, Sheep, Pigs, Dogs and Cats

6. INDICATION(S)

For the treatment of infections caused by a wide range of Gram-positive and Gram-negative pathogenic bacteria.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake the vial before use

Cattle, Sheep and Pigs: By intramuscular injection only.

Dogs and Cats: By subcutaneous or intramuscular injection.

Dosage rate is 7 mg per kg bodyweight, for up to five days (equivalent to 0.25 ml per 5 kg a day). A separate injection site should be used for each administration.

ANIMAL	WEIGHT (kg)	DOSAGE VOLUME (ml)
Cattle	450 kg	20.0 ml
Sheep	65 kg	2.0 ml
Pig	150 kg	7.0 ml
Dog	20 kg	1.0 ml
Cat	5 kg	0.25 ml

Swab the septum before removing each dose. Use a dry sterile needle and syringe

8. WITHDRAWAL PERIOD

Milk for human consumption must not be taken from a cow during treatment. With cows milked twice daily, milk for human consumption may only be taken from 24 hours after the last treatment. Not for use in sheep producing milk for human consumption.

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 18 days from the last treatment.

Sheep may be slaughtered for human consumption only after 10 days from the last treatment. Pigs may be slaughtered for human consumption only after 16 days from the last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

Not suitable for intravenous or intrathecal administration.

As with other penicillins, amoxicillin should not be used in rabbits, hamsters, gerbils or guinea pigs.

Not effective against beta-lactamase producing organisms.

Occasional tissue reaction may result from use of this product.

Penicillin/cephalosporin may occasionally cause severe allergic reactions.

See package leaflet for operator warnings

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.
Protect from light.
Keep out of the reach and sight of children.
Following withdrawal of the first dose, use the product within 28 days.
Discard unused material.
This product does not contain an antimicrobial preservative.

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 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
Newry
Co. Down
BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4071

17. MANUFACTURER'S BATCH NUMBER

PACKAGE LEAFLET:

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
Northern Ireland.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Betamox 150 mg/ml Suspension for Injection

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

Betamox injection is an off white sterile suspension containing 150 mg/ml amoxicillin as Amoxicillin Trihydrate (17.21 % w/v) and the antioxidants butylated hydroxytoluene 0.08mg/ml and butylated hydroxyanisole 0.08 mg/ml.

Chemically, Amoxicillin is 6[D(-) - ∝- amino-p-hydroxy-phenylacetamido] penicillanic acid.

4. INDICATION(S)

Betamox Injection 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: *Actinobacillus equuli*, *Actinomyces bovis, Actinobacillus lignieresi Bacillus anthracis, Bordetella bronchiseptica, Clostridium* species, *Corynebacterium* species, *Erysipelothrix rhusiopathiae, Escherichia coli, Fusiformis* species, *Haemophilus* species, *Moraxella* species, *Pasteurella* species, *Proteus mirabilis*, *Salmonella* species, Staphylococci and Streptococci in cattle sheep , pigs, dogs and cats.

5. CONTRAINDICATIONS

This product is not suitable for administration via intravenous or intrathecal routes. Not effective against beta-lactamase producing organisms.

As with other penicillins, amoxicillin should not be administered orally or parenterally in rabbits, hamsters, gerbils and guinea pigs.

Not effective against beta-lactamase producing organisms.

6. ADVERSE REACTIONS

Occasional local tissue reaction may result from use of this product.
If you notice any serious effects or other effects not mentioned in this leaflet, 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

Cattle, Sheep and Pigs: By intramuscular injection only.

Dogs and Cats: By subcutaneous or intramuscular injection.

Dosage rate is 7 mg per kg bodyweight, for up to five days.

Massage the injection site. A separate injection site should be used for each administration.

ANIMAL	WEIGHT (kg)	DOSAGE VOLUME (ml)
Cattle	450 kg	20.0 ml
Sheep	65 kg	2.0 ml
Pig	150 kg	7.0 ml
Dog	20 kg	1.0 ml
Cat	5 kg	0.25 ml

(Guide-dose volume is equivalent to 0.25 ml per 5 kg bodyweight).

9. ADVICE ON CORRECT ADMINISTRATION

Normal aseptic precautions should be observed. Shake vial before use. This product does not contain an antimicrobial preservative. Swab the septum before removing each dose. Use a dry, sterile needle and syringe.

10. WITHDRAWAL PERIOD(S)

Milk for human consumption must not be taken from a cow during treatment. Milk for human Milk for human consumption must not be taken from a cow during treatment. Milk for human consumption may only be taken after 24 hours from the last treatment.

Not for use in sheep producing milk for human consumption.

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 18 days from the last treatment. Sheep may be slaughtered for human consumption only after 10 days from the last treatment. Pigs may be slaughtered for human consumption only after 16 days from the last treatment. consumption may only be taken after 24 hours from the last treatment.

Not for use in sheep producing milk for human consumption.

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 18 days from the last treatment. Sheep may be slaughtered for human consumption only after 10 days from the last treatment. Pigs may be slaughtered for human consumption only after 16 days from the last treatment.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC.
Keep out of the reach and sight of children.
Shake the vial before use
Following withdrawal of the first dose, use the product within 28 days. Discard unused material. When the container is broached (opened) for the first time, using the in0use 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)

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

High levels of Amoxicillin are found in kidney, urine, liver and bile.
Also important is the rapid bactericidal action after absorption due to its wide distribution.
In common with other penicillins an absence of toxicity is apparent even at high dose levels.
Animals with functional rumens should only be treated parenterally.

PACKAGE QUANTITIES:

50 ml and 100 ml multidose glass vials
50 ml and 100 ml plastic vials

Not all package sizes may be marketed.

DISTRIBUTED BY:

Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
BT35 6QQ
Co. Down
Northern Ireland

MARKETING AUTHORISATION NUMBER:

Vm 02000/4071

POM-V

To be supplied only on veterinary prescription.

FOR ANIMAL TREATMENT ONLY

Approved 28 October 2022