PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Container Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimoxyl LA, 150 mg/ml amoxicillin, suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

150 mg/ml Amoxicillin.

CONCENTRATION**:** Each ml contains: 150mg amoxicillin as amoxicillin trihydrate in a sterile long acting, non-aqueous base.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle, sheep, pigs and dogs.

6. INDICATION(S)

For the control and treatment of respiratory and other infections in cattle and sheep caused by amoxicillin susceptible Gram-positive and Gram negative bacteria only. For the treatment of infectious diseases in pigs and dogs caused by or associated with organisms sensitive to amoxicillin.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage and Administration:
Cattle, Sheep & Pigs: To be injected by the intramuscular route.
Dogs: To be injected subcutaneously.

Dosage rate of 15 mg amoxicillin per kg bodyweight. This is equivalent to 1 ml/10 kg. The injection site should be massaged after injection. The maximum injection volume at any one site is: Cattle: 20 ml; Sheep: 4 ml; Pigs: 5 ml; Dogs: 2.5 ml. Larger dose volumes should be divided and given into separate sites.

One repeat administration may be given after 48 hours. For intramuscular injections, separate site(s) to the first injection(s) must be used.

8. WITHDRAWAL PERIOD

Withdrawal Periods;

Cattle: Meat and offal: 21 days
Milk: 72 hours

Sheep: Meat and offal: 19 days
Not authorised for use in sheep producing milk for human consumption.

Pigs: Meat and offal: 24 days.

9. SPECIAL WARNING(S), IF NECESSARY

FURTHER INFORMATION WARNINGS & CONTRA-INDICATIONS: SEE PACKAGE LEAFLET

PHARMACEUTICAL PRECAUTIONS: This product does not contain an antimicrobial preservative. Swab the septum before removing each dose. Use a dry, sterile needle and syringe. Following withdrawal of the first dose, use the product within 28 days. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority

Once broached, discard by / /

Shake vial before use.

10. EXPIRY DATE

Expiry Date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C
Protect from light

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For Animal Treatment Only.
UK authorised veterinary medicinal product.
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

MA holder:
Bimeda Animal Health Limited
2 / 3 / 4 Airton Close,
Tallaght, Dublin 24,
Ireland

Distributor:
Bimeda ®
Cross Vetpharm Group UK Ltd.
Unit 2, Bryn Cefni
Llangefni
Anglesey
LL77 7XA
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4010

17. MANUFACTURER'S BATCH NUMBER

Batch No:
Manuf. Date:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Container Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimoxyl LA, 150 mg/ml amoxicillin, suspension for injection.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

150 mg/ml Amoxicillin.

Each ml contains 150mg amoxicillin (as amoxicillin trihydrate).

A long acting sterile suspension of amoxicillin for injection.

Amoxicillin

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle, sheep, pigs and dogs.

6. INDICATION(S)

Not stated on carton.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For use in cattle, sheep and pigs by intramuscular injection and dogs by subcutaneous injection.

8. WITHDRAWAL PERIOD

Withdrawal Periods;
Cattle: Meat and offal: 21 days
Milk: 72 hours

Sheep: Meat and offal: 19 days
Not authorised for use in sheep producing milk for human consumption.

Pigs: Meat and offal: 24 days.

9. SPECIAL WARNING(S), IF NECESSARY

Further information and user warnings – see package leaflet.

10. EXPIRY DATE

Expiry Date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C
Protect from light

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

Not stated on carton.

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

Manufactured by:
Bimeda Animal Health Limited, 2 / 3 / 4 Airton Close, Tallaght, Dublin 24, Ireland

Distributed by:
Bimeda ®
Cross Vetpharm Group UK Ltd.
Unit 2, Bryn Cefni
Llangefni
Anglesey
LL77 7XA
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4010

17. MANUFACTURER'S BATCH NUMBER

Batch No:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE}

Not applicable

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE}

Not applicable

PACKAGE LEAFLET

Bimoxyl LA, 150 mg/ml Suspension for Injection for cattle, sheep, pigs and dogs.

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE.

Marketing Authorisation Holder:
Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght, Dublin 24
Ireland

Manufacturer responsible for batch release:
Laboratorios Syva S.A.
Av. Párroco Pablo Díez, 49-57
24010 León (Spain)

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimoxyl LA, 150 mg/ml Amoxicillin Suspension for Injection

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

Each ml contains: 150 mg amoxicillin as Amoxicillin Trihydrate in a sterile long acting non aqueous base.

4. INDICATIONS

For the control and treatment of respiratory and other infections in cattle and sheep caused by amoxicillin susceptible Gram-positive and Gram-negative bacteria only. For the treatment of infectious diseases in pigs and dogs caused by or associated with organisms sensitive to amoxicillin. Not effective against Beta-lactamase producing organisms.

5. CONTRAINDICATIONS

Not suitable for intravenous or intrathecal administration.
Not for use in ewes producing milk for human consumption or food processing.
Not to be administered to small herbivores.
Do not use in known cases of hypersensitivity to beta-lactam antibiotics.

6. ADVERSE REACTIONS

Occasional local reaction of a transient nature may occur at the site of injection.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

For use in cattle, sheep, pigs and dogs.

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

Cattle, Sheep & Pigs.
To be injected by the intramuscular route.

Dogs:
To be injected subcutaneously.

Dosage rate of 15 mg amoxicillin per kg bodyweight. This is equivalent to 1 ml/10kg. One repeat administration may be given after 48 hours. For intramuscular injections, separate site(s) to the first injection(s) must be used.

9. ADVICE ON CORRECT ADMINISTRATION

The injection site should be massaged after injection.
The maximum injection volume at one site is:
Cattle: 20ml; Sheep: 4 ml; Pigs: 5 ml; Dog: 2.5 ml.
Larger dose volumes should be divided and given into separate sites.
Use a dry syringe for extraction of suspension to avoid hydrolysis of amoxicillin.
An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.
The closure should not be pierced more than 30 times.

10. WITHDRAWAL PERIOD

Cattle: Meat and offal: 21 days
Milk: 72 hours
Sheep: Meat and offal: 19 days
Not authorised for use in sheep producing milk for human consumption.
Pigs: Meat and offal: 24 days.

11. SPECIAL STORAGE PRECAUTIONS

For animal treatment only.
Keep out of the sight and reach of children.
Do not store above 25°C.
Protect from light.
Shake the 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.
Following withdrawal of the first dose, use the product within 28 days.

12. SPECIAL WARNING(S)

USER PRECATIONS AND OTHER WARNINGS.

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.

4. Wash hands after use.

It is not recommended to administer bactericidal and bacteriostatic antibiotics concomitantly.
Not effective against Beta-lactamase producing organisms.

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

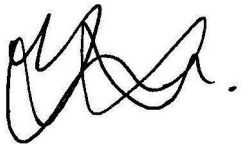
September 2022

15. OTHER INFORMATION

UK authorized veterinary medicinal product.
MA No. Vm 50146/4010

Legal category: **POM-V** To be supplied only on veterinary prescription.
Package quantities:
100 ml clear Type I glass vials fitted with red or grey bromobutyl rubber stoppers and sealed with plain aluminium caps.
100 ml Polyethylene terephthalate (PET) vials with a chlorobutyl stopper and an aluminium cap with plastic flipoff seal.

Distributed by:
Bimeda ®
Cross Vetpharm Group UK Ltd.
Unit 2, Bryn Cefni
Llangefni
Anglesey
LL77 7XA
United Kingdom



Approved: 14 September 2022