ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING - COMBINED LABEL AND PACKAGE LEAFLET

Pack Label 250 ml & 1 L
[There is no carton for the 1 L packs.
Package leaflet information will be printed on the immediate packaging]

1. Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

Marketing Authorisation Holder and Manufacturer responsible for Batch release:
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

TEL: 01248 725400 e-mail: uksales@bimeda.com

2. Name of the veterinary medicinal product

Bimamix Oral Suspension for Calves
Sulfadiazine
Neomycin

3. Statement of the active substance (s) and other ingredients

Active substances:	per ml
Sulfadiazine	150 mg
Neomycin (as neomycin sulphate)	25 mg

List of excipients:

Methyl Parahydroxybenzoate (E218)	2 mg (preservative)
Propyl Parahydroxybenzoate (E216)	0.2 mg (preservative)
Carmosine (E122)	0.05 mg

4. Pharmaceutical form

Oral Suspension.

5. Package Size

250 ml
1 L

6. Indication(s)

For the treatment of diarrhoea in pre-ruminant calves associated with infections caused by organisms known to be, or suspected of being, susceptible to the combination of sulfadiazine and neomycin.

7. Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.
Do not exceed the recommended dosage or the period of treatment.
Do not use local anaesthetics of the procaine group during treatment as they are antagonistic to the sulphonamide component.
Do not use in calves with a functional rumen.
Do not use in lactating cows.
Do not use in foals and horses.

8. Adverse reactions

Sulphonamides may very rarely cause severe allergic reactions. Chronic usage of oral neomycin may result in bacterial or fungal superinfections.

The frequency of adverse reactions is defined using the following convention
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- 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 on this label or you think that the medicine has not worked, please inform your veterinary surgeon.

9. Target species

Pre-ruminant calves.

10. Dosage for each species, route(s) and method of administration

Shake the bottle well before use.
Administration is by oral drench.

4 ml per 10 kg bodyweight twice daily for a maximum period of 5 days. This equates to 60 mg/kg Sulfadiazine and 10 mg/kg Neomycin twice daily. To ensure correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

11. Advice on correct administration

Not applicable.

12. Withdrawal period(s)

Withdrawal period(s):

Meat & offal: 28 days. Not intended for use in animals producing milk for human consumption.

13. Special storage precautions

Do not store above 25°C

14. Special warning(s)

Special warnings for each target species:
Concurrent intravenous fluid therapy should be considered in dehydrated calves. Parenteral antibiotic treatment should be considered if a clinical response is not seen after 48 hours treatment.

Special precautions for use in animals:
Official, national and regional antimicrobial policies should be taken into account when the product is used.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Care should be taken to avoid contact with the skin. Wash hands after use. Sulphonamides may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to sulphonamides may lead to cross reaction with other antibiotics. Allergic reaction to these substances may occasionally be serious.

1. Do not handle this product if you know you are sensitive to sulphonamides.
2. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning.

Pregnancy, lactation or lay:
The product is intended for use in calves only.
Do not use in lactating cows.

Interaction with other medicinal products and other forms of interaction:
There is interaction and antagonism between sulphonamides and the Vitamin B Complex. Do not use local anaesthetics of the procaine group during treatment, as they are antagonistic to the sulphonamide component.

Overdose (symptoms, emergency procedures, antidotes):
Good tolerance has been confirmed in calves at x3 and x5 times the recommended dose rate.

Incompatibilities:
There is interaction and antagonism between sulphonamides and the Vitamin B Complex. Do not use local anaesthetics of the procaine group during treatment, as they are antagonistic to the sulphonamide component.

15. Special precautions for the disposal of unused product or waste materials, if any

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

16. Date on which the label was last approved

17. Other information

Available in 250 ml and 1 L pack size.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

18. The words "For animal treatment only" and conditions or restrictions regarding supply and use, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

POM-V

19. The words "Keep out of the sight and reach of children"

Keep out of the sight and reach of children.

20. Expiry date

<EXP {month/year}>
Shelf life of the veterinary medicinal product as packaged for sale: 18 months
Shelf life after first opening of the immediate packaging: 28 days
Discard date ___/___/___

21. Marketing authorisation number(s)

Vm 50146/4022

22. Manufacturer’s batch number

<Batch> <Lot>

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimamix Oral Suspension for Calves
Sulfadiazine
Neomycin

2. STATEMENT OF ACTIVE SUBSTANCES

Active substances:	per ml
Sulfadiazine	150 mg
Neomycin (as neomycin sulphate)	25 mg

3. PHARMACEUTICAL FORM

Oral Suspension

4. PACKAGE SIZE

250 ml

50 ml dosing syringe

5. TARGET SPECIES

Pre-ruminant calves

6. INDICATION(S)

For the treatment of diarrhoea in pre-ruminant calves associated with infections caused by organisms known to be, or suspected of being, susceptible to the combination of sulfadiazine and neomycin.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
Administration is by oral drench.

4 ml per 10 kg bodyweight twice daily for a maximum period of 5 days. This equates to 60 mg/kg Sulfadiazine and 10 mg/kg Neomycin twice daily. To ensure correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):

Meat & offal: 28 days. Not intended for use in animals producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the label before use.
Sulphonamides may very rarely cause severe allergic reactions. Care should be taken to avoid contact with the skin.

10. EXPIRY DATE

EXP:{month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

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

For animal treatment only.
To be supplied only on veterinary prescription. **POM-V**

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder and Manufacturer responsible for Batch release:
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 50146/4022

17. MANUFACTURER'S BATCH NUMBER

Batch No:

Approved 08 September 2020