# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimamix, Oral Suspension for Calves

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

**Active substances:**

| | |
|---|---|
| Sulfadiazine | 150 mg/ml |
| Neomycin (as neomycin sulphate) | 25 mg/ml |

**Excipients:**

| | |
|---|---|
| Methyl Parahydroxybenzoate | 2.0 mg/ml |
| Propyl Parahydroxybenzoate | 0.2 mg/ml |
| Carmoisine E122 | 0.05 mg/ml |

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Oral suspension.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Pre-ruminant calves

### 4.2 Indications for use, specifying the target species

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.

### 4.3 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.

## 4.4 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.

## 4.5 Special precautions for use

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.

## 4.6 Adverse reactions (frequency and seriousness)

Chronic usage of oral neomycin may result in bacterial or fungal superinfections.

## 4.7 Use during pregnancy, lactation or lay

The product is intended for use in calves only.
Do not use in lactating cows.

## 4.8 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.

## 4.9 Amounts to be administered and administration route

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.

### 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Good tolerance has been confirmed in calves at x3 and x5 times the recommended dose rate.

### 4.11 Withdrawal period(s)

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

## 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antidiarrheals, intestinal anti-inflammatory/antiinfective agents, intestinal antiinfectives, antibiotics
ATCvet code: QA07AA51

### 5.1 Pharmacodynamic properties

Sulphadiazine is a broad spectrum antimicrobial agent. It acts by interfering with the biosynthesis of folic acid in bacterial cells, competitively preventing para-aminobenzoic acid (PABA) from incorporation into folic acid molecule.

Neomycin is the isomeric mixture of Neomycin Band C. It has a rapid dose related bactericidal action on susceptible microorganisms. The antibacterial action is directed primarily against aerobic gram negative bacteria.

### 5.2 Pharmacokinetic particulars

Sulfadiazine is rapidly absorbed from the gastrointestinal tract and widely distributed to all tissues and body fluids. The sulphonamides are eliminated by a combination of renal excretion and biotransformation.

Neomycin is poorly absorbed from the gastrointestinal tract, has a short half-life and is nearly all excreted unchanged from the gastrointestinal tract.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Methyl parahydroxybenzoate
Propyl parahydroxybenzoate
Carmoisine E122
Light Kaolin
Citric Acid Anhydrous
Sodium Citrate
Xanthan Gum
Povidone 90
Propylene Glycol
Polysorbate 20
Simethicone Emulsion
Water Purified

### 6.2 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.

### 6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months
Shelf life after first opening the immediate packaging: 28 days

### 6.4 Special precautions for storage

Do not store above 25ºC.

### 6.5 Nature and composition of immediate packaging

250 ml and 1 litre white, high density polyethylene bottles. The closure is a tamper evident cap composed of a polypropylene copolymer.
A 50ml dosing syringe is supplied with the 250ml presentation only
Not all pack sizes may be marketed.

### 6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused product or waste materials should be disposed of in accordance with national requirements.

## 7. MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

## 8. MARKETING AUTHORISATION NUMBER

Vm 50146/4022

## 9. DATE OF FIRST AUTHORISATION

12 June 2007

## 10. DATE OF REVISION OF THE TEXT

October 2018

Approved: 24 October 2018