1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimadine powder for oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each individual sachet contains:

Active substance:

Sulfadimidine 25 g

Excipient:

Qualitative composition of excipients and other constituents
Silicon dioxide

A white or almost white powder.

3. CLINICAL INFORMATION

3.1 Target species

Calves.

3.2 Indications for use for each target species

For the treatment of diseases in monogastric calves caused by or associated with organisms sensitive to sulfadimidine.

3.3 Contraindications

Do not use local anaesthetics of the procaine group during treatment as they are antagonistic.
Do not exceed the recommended dosage or the period of treatment.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Do not exceed the recommended dosage or the period of treatment.
The dose should be calculated to the nearest gram.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Not applicable.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Calves:

Undetermined frequency (cannot be estimated from the available data)	Vitamin deficiency[1,2] Agranulocytosis[2] Haemolytic anaemia[2]

[1]Vitamin K deficiency
[2]Prolonged treatment may lead to risk of occurrence

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also the carton for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Not applicable.

3.8 Interaction with other medicinal products and other forms of interaction

The procaine of procaine benzylpenicillin and of the procaine group of local anaesthetics is an analogue of PABA and will antagonise sulfonamides. There is interaction and antagonism between sulfonamides and vitamin B complex.

3.9 Administration routes and dosage

Oral use.
Initial dose: 2 g per 10 kg bodyweight (equivalent to 1 sachet per 125 kg bodyweight), followed by daily doses of 1 g per 10 kg bodyweight (equivalent to 1 sachet per 250 kg bodyweight) for a further two days only.

The required dose should be added to twice its own volume of water, the sulfadimadine should then be suspended in the water by vigorously shaking the vessel, the material should then be administered as an oral drench. Suspended drench should be prepared individually for each animal and used immediately.

Care should be taken to ensure that the entire dose is administered.

To ensure a correct dosage, body weight should be determined as accurately as possible.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Do not exceed the recommended dosage or the period of treatment.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Meat and offal: 28 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01EQ03

4.2 Pharmacodynamics

Sulfadimidine is a bacteriostatic anti-bacterial agent that interferes with folic acid synthesis in susceptible bacteria. It diffuses freely throughout the body tissues. It crosses the placenta into the foetal circulation and is excreted in low concentrations in milk.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: 24 hours.

5.3 Special precautions for storage

Do not store above 25 ºC.

5.4 Nature and composition of immediate packaging

White polyethylene / aluminium sachets.

Pack sizes:
Carton containing 100 x 25 g sachets.
Carton containing 200 x 25 g sachets.

Not all pack sizes may be marketed.

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

Partly used sachets should be placed in a suitably labelled, closed container to await disposal by a registered contractor.

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited.

7. MARKETING AUTHORISATION NUMBER(S)

VPA22033/037/001

8. DATE OF FIRST AUTHORISATION

01/10/1988

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

17/01/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).