1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimadine Powder for Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each individual sachet contains :
Active substance

Sulfadimidine 25g

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder for Oral Suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Calves

4.2 Indications for use, specifying the target species

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

4.3 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 animals known to be hypersensitive to the active ingredient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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

None.

4.6 Adverse reactions (frequency and seriousness)

Prolonged treatment may lead to risk of vitamin K deficiency, agranulocytosis and haemolytic anaemia.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 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.

4.9 Amounts to be administered and administration route

For oral administration.

Initial dose: 2 g per 10 kg (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.

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

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

4.11 Withdrawal period(s)

Animals must not be slaughtered for human consumption during treatment. Animals may be slaughtered for human consumption only after 28 days from the last treatment.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antibacterials for systemic use, sulfonamides
ATCvet Code: QJ01EQ03

5.1 Pharmacodynamic Properties

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Silicon dioxide

6.2 Incompatibilities

None known.

6.3 Shelf life

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

6.4. Special precautions for storage

Do not store above 25ºC.

6.5 Nature and composition of immediate packaging

White polyethylene / aluminium sachets containing 25 g powder.
100 x 25 g sachets in cardboard boxes.
200 x 25 g sachets in cardboard boxes.

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

Partly used sachets should be placed in a suitably labelled, closed container to await disposal by a registered contractor.
Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7. MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

8. MARKETING AUTHORISATION NUMBER(S)

VPA22033/037/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01/10/1988

10 DATE OF REVISION OF THE TEXT

23/02/2024