

IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10126/027/001**
Case No: 7004607

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Bimeda Chemicals

Broomhill Road, Tallaght, Dublin 24., Ireland

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Bimadine Powder for Oral Suspension

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **30/09/2008**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, this authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

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

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 or IMMUNOLOGICAL 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.

5.2 Pharmacokinetic properties

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

Silicone dioxide

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf-life after reconstitution according to directions: 24 hours.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

White polyethylene / aluminium sachets containing 25 g powder.

Packaged as 100 x 25 g sachets in cardboard boxes.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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 Chemicals Ltd.,
Broomhill Road,
Tallaght,
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10126/027/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT