

IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10126/020/001**
Case No: 7004743

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:

Bimotrim Co Injection

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

Bimotrim Co Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances

Sulfadoxine 200 mg

Trimethoprim 40 mg

Excipients

Sodium Formaldehyde Sulfoxylate 1 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

The injection may be used in the treatment of a wide range of diseases and conditions of bacterial origin in cattle. Bimotrim Co Injection is active against Gram-positive and Gram negative bacteria including: Streptococci, Straphylococci, *Salmonella* spp., *Pasteurella* spp., Pneumococci, *Escherichia coli*, *Brucella* spp., *Proteus* spp., *Vibrio* spp., *Corynebacteria* and *Klebsiella*.

4.3 Contraindications

Do not use in animals with a known hypersensitivity to the active substances.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

None.

4.6 Adverse reactions (frequency and seriousness)

Injection site reaction may occur.

4.7 Use during pregnancy, lactation or lay

The safety of this product when used in pregnant animals has not been specifically studied. However, the company are unaware of any reports of adverse effects on the foetus when the product is used in this sub-population of animals.

4.8 Interaction with other medicinal products and other forms of interaction

Because of the competitive action of the sulfonamides, their activity may be antagonised by the presence of any of the following.

1. Para-aminobenzoic acid (PABA) and related compounds particularly local anaesthetics with a PABA nucleus such as procaine, butacaine and benzocaine, but also compounds associated with those such as procaine penicillin. It is recommended that local anaesthetics of the procaine group should not be used during treatment with Bimotrim Co Injection.
2. Some members of the Vitamin B complex, such as nicotinamide, folic acid, choline and precursors of these.
3. Proteins which combine loosely with the sulfonamides and at least temporarily reduce their antibacterial activity. Gelatin, albumin, peptone and serum protein all antagonise the sulfonamides. Associated with this group are products of cell and tissue death, especially pus, which also acts as a non-vascular, mechanical barrier.
4. A number of other compounds, including enzymes, glucose and mercuric chloride, are all reported to have antagonistic effects against sulphonamides.

4.9 Amounts to be administered and administration route

1 ml per 16 kg bodyweight, equivalent to 12.5 mg sulfadoxine and 2.5 mg trimethoprim per kg bodyweight.

Treatment must be given until 2 days after clinical signs have resolved, up to a maximum of 5 days.

For administration by intramuscular injection or slow intravenous injection.

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

Do not exceed the recommended dose or treat animals for more than 5 consecutive days.

4.11 Withdrawal Period(s)

Meat and offal: 5 days

Milk: 48 hours

Milk for human consumption must not be taken from a cow during treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, combinations of sulfonamides and trimethoprim.

ATCvet code: QJ01EW13

5.1 Pharmacodynamic properties

The two active ingredients (sulfadoxine and trimethoprim) produce a sequential double blockade of bacterial synthesis of folic acid, giving a level of activity many times greater than that obtained from either drug alone. Both are eliminated from plasma partly by metabolism and partly by excretion of the unchanged compounds in urine or faeces.

5.2 Pharmacokinetic properties

50% of total trimethoprim (TMP) is bound to plasma protein whereas the binding of sulfadoxine depends on total plasma concentration and varies between 14 and 72%. Trimethoprim has a high therapeutic index and a wide antibacterial activity in vitro. Trimethoprim is more lipophilic and penetrates tissues better than sulfadoxine which is reflected by its consistently higher distribution volume. Highest concentrations of trimethoprim are found in liver and kidney while sulfadoxine is detected in high concentrations in liver, kidney, duodenum and lung.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Hydroxide

Sodium Formaldehyde Sulfoxylate

Glycerol formal

Water for Injections

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years

Shelf-life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

Do not store above 25°C.

Protect from light.

6.5 Nature and composition of immediate packaging

100 ml amber, Type II glass multidose vials, sealed with a butyl rubber stopper and capped with aluminium overseal.

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

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

7 MARKETING AUTHORISATION HOLDER

Bimeda Chemicals Ltd.,
Broomhill Road,
Tallaght,
Dublin 24.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10126/020/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT