SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Bimotrim Co Injection Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Constituents	per ml	
Sulfadoxine	200 mg	
Trimethoprim	40 mg	
Relevant Constituents of the Excipient	**per ml**	**Function**
Sodium Formaldehyde Sulphoxylate	1mg	Antioxidant
*Glycerol Formal	758.2 mg	Co-solvent

*Glycerol Formal contains the following antioxidants:
Thiodipropionic acid (MS) – 0.01% equivalent to 0.0062% in the final solution.
N-Propyl Gallate (MS) – 0.02% equivalent 0.0124% in the final solution.
Disodium Edetate (Ph Eur) – 0.02% equivalent to 0.0124% in the final solution.

For full list of excipients refer to section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle and horses.

4.2 Indications for use, specifying the target species

The in *vitro* activity covers most common Gram-positive and Gram-negative bacteria including *Actinobacillus* spp., *Actinomyces bovis*, *Bordetella* spp., *Corynebacterium* spp., *Klebsiella* spp., *Listeria monocytogenes*, *Nocardia* spp., *Pasteurella* spp., *Proteus* spp., *Salmonella* spp., *Staphylococcus* spp., and *Streptococcus* spp.

Indications: The injection may be used in the treatment of a wide range of diseases and conditions of bacterial origin in cattle and horses.
Respiratory infections of bacterial origin including pneumonia, rhinitis, bronchitis and secondary bacterial infections following virus pneumonia mycoplasmal infections.

Urogenital tract infections including cystitis, vaginitis, urethritis, nephritis and metritis.
Alimentary tract infections, neonatal diarrhoea, salmonellosis and post- weaning enteritis.

4.3 Contraindications

Do not administer by the intraperitoneal or subcutaneous route.
Do not administer to horses exhibiting cardiac arrhythmias. Such arrhythmias may be associated with the administration of certain anaesthetic and sedative agents.

4.4 Special warnings for each target species

Very occasionally, temporary irritating swellings may appear at the site of injection.

4.5 Special precautions for use

i. Special precautions for use in animals

The following warnings are applicable to all Trimethoprim Sulfonamide combinations for use in the horse.

1. Cardiac and respiratory shocks in horses have been observed, mostly after intravenous injection.
2. The injection solution should be approximately at body temperature. At the first signs of intolerance, the injection should be interrupted and shock treatment initiated. The product should be injected slowly over as long a period as is reasonably practical.
3. The intravenous route of administration is contra-indicated in the case of previous or concurrent administration of central nervous system depressants (e.g. anaesthetics, neuroleptics).
4. The possibility of an anaphylactic or hypersensitivity reaction occurring following administration on rare occasions must be borne in mind.
5. As with all trimethoprim sulphonamide formulations the possibility of potential damage to the kidney or liver or haematopoetic system should be considered.

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

Care should be taken to avoid accidental injection and 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 reactions with other antibiotics. Allergic reactions to these substances may occasionally be serious.

Do not handle this product if you know you are sensitive to sulphonamides.
If you develop symptoms following exposure such as skin rash, you should seek medical advice and show the doctor this warning.

4.6 Adverse reactions (frequency and seriousness)

Very occasionally, temporary irritating swellings may appear at the site of injection.

4.7 Use during pregnancy, lactation or lay

Studies during pregnancy have not been conducted. Use with care in pregnant animals.

4.8 Interaction with other medicinal products and other forms of interactions

Because of the competitive action of the sulphonamides, 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 sulphonamides and at least temporarily reduce their antibacterial activity. Gelatin, albumin, peptone and serum protein all antagonise the sulphonamides. 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

Dose: 15mg/kg (equivalent to 1 ml per 16 kg bodyweight) daily. Daily dosing should be repeated for two days after symptoms have resolved up to a maximum of 5 days.
Route of administration:
Cattle: By slow intravenous or intramuscular injection. Intramuscular injection is the preferred route and should be given into the neck.
Horses: By slow intravenous injection.

4.10 Overdose (symptoms, emergency procedure. antidotes), if necessary

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

4.11 Withdrawal periods

Cattle: Meat & offal: 10 days. Milk: 60 hours

Horses: Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

5. PHARMACOLOGICAL 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.

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 sulphadoxine, which is reflected by its consistently higher distribution volume. Highest concentrations of Trimethoprim are found in liver and kidney while sulphadoxine is detected in high concentrations in liver, kidney, duodenum and lung.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Formaldehyde Sulphoxylate
Glyerol Formal containing:
Thiodipropionic acid
N-Propyl Gallate
Disodium Edetate
Water for Injections
Sodium Hydroxide (for pH adjustment)
Hydrochloric Acid (for pH adjustment)

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 opening the immediate packaging: 28 days

6.4 Special precautions for storage

Do not freeze.
Do not store above 25°C.
Protect from light.
Following withdrawal of the first dose use the product within 28 days.
Discard unused material.

6.5 Nature and contents of immediate packaging

A clear, sterile aqueous solution contained in 100 ml amber, Type II glass, multidose vials.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 50146/4027

9. DATE OF FIRST AUTHORISATION

22 December 1992

10. DATE OF REVISION OF THE TEXT

October 2018

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