1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimotrim Co Solution for Injection for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Sulfadoxine 200 mg
Trimethoprim 40 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium Formaldehyde Sulfoxylate	1 mg
Sodium Hydroxide	
Hydrochloric Acid	
Glycerol formal	
Water for Injections	

A clear pale pink-brown liquid.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

The injection may be used in the treatment of a wide range of diseases and conditions of bacterial origin in cattle.
The veterinary medicinal product 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.*

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances 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:
Not applicable.

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

Cattle:

Undetermined frequency (cannot be estimated from the available data)	Injection site reaction

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 its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
The safety of the veterinary medicinal product has not been established during pregnancy. However, the company are unaware of any reports of adverse effects on the foetus when this veterinary medicinal product is used in this sub-population of animals.

3.8 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 this veterinary medicinal product.
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.

3.9 Administration routes and dosage

Intramuscular or intravenous use.

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.

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

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

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: 5 days.
Milk: 48 hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QJ01EW13.

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 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.

5.3 Special precautions for storage

Do not store above 25 °C.
Protect from light.

5.4 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.

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

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)

VPA 22033/038/001

8. DATE OF FIRST AUTHORISATION

01/10/1988

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

12/01/2026

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).