

BIMOTRIM CO INJECTION



BENEFITS

- Synergistic combination of Sulphadoxine and Trimethoprim, for enhanced antibacterial activity
- Active against Gram-negative and Gram-positive organisms
- Wide species protection
- Indicated for the treatment of a range of diseases
- Short withdrawals

PACKAGING

| LIST NO. | UNIT PACKAGE | CASE SIZE |
|----------|--------------|-----------|
| 1BIM018 | 100ml | 12 |

See reverse side for full indications, administration and dosage.



BIMOTRIM CO INJECTION

Presentation

A clear, pale pink/brown sterile, aqueous solution for parenteral administration. Each ml contains: 200mg Sulfadoxine and 40mg Trimethoprim.

Target Species

Cattle and horses.

Indications for use

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.

Contra-indications

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.

Special warnings for each target species

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

Special Precautions For Use

(i) Special precautions for use in animals

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

- Cardiac and respiratory shocks in horses have been observed, mostly after intravenous injection.
- 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.
- 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).
- The possibility of an anaphylactic or hypersensitivity reaction occurring following administration on rare occasions must be borne in mind.
- As with all trimethoprim sulphonamide formulations the possibility of potential damage to the kidney or liver or haematopoietic system should be considered

(ii) Special precautions to be taken by person administering the medicinal product

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.

Adverse reactions:

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

Use During Pregnancy, Lactation or lay

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

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:

- 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.

- Some members of the Vitamin B complex, such as nicotinamide, folic acid, choline and precursors of these.
- 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.
- A number of other compounds, including enzymes, glucose and mercuric chloride, are all reported to have antagonistic effects against sulphonamides.

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.

Overdose (symptoms, emergency procedure. Antidotes), if necessary

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

Withdrawal Periods

Milk for human consumption must not be taken during treatment.

With cows milked twice daily, milk for human consumption may only be taken from 60 hrs. (i.e. 5th milking) from the last treatment.

With other milking routines, milk may be taken for human consumption only after the same period from last treatment (e.g. with 3 times a day milking, milk for human consumption may only be taken at the 8th milking).

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 10 days from last treatment. 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.

6.2 Incompatibilities (major)

None known.

6.3 Shelf Life, when necessary after reconstitution of the product or when the container is opened for the first time.

- Shelf-Life of the veterinary medicinal product as packaged for sale: 2 years.
- Shelf-life after opening the immediate packaging: 28 days

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.

Special Precautions for the disposal of unused veterinary medicinal products or waste materials derived from such products, if appropriate

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

Marketing Authorisation Holder

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

Marketing Authorisation Number

Vm: 02676/4156

Legal Category POM-V

Pack quantity Multi-dose 100ml vials

This information should be used as a general guide, for more specific instructions on the use of Bimeda® products always read the product label carefully.

