



1.3 Product information

1.3.1 Summary of product characteristics

1 Name of the veterinary medicinal product

Sulfamethoxazole 2000mg + Trimethoprim 400mg Bolus

2 Qualitative and quantitative composition

Active ingredients (per bolus):

Sulfamethoxazole – 2000mg

Trimethoprim – 400mg

3 Pharmaceutical form

Bolus

Yellow bolus.

4. Clinical particulars

4.1 Target species

Cattle and sheep

4.2 Indications for use, specifying the target species

It is used for urinary tract infection, respiratory tract infection and skin and soft tissue infections caused by *Streptococcus pyogenes*, *Salmonella* and *Actinobacillus pleuropneumoniae*, etc.

4.3 Contraindications

Do not administer in animals with sensitivity to sulfonamides.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

None.

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

Protective gloves should be worn to avoid skin sensitisation, which may occur when crushing the bolus of the product.

Wash hands after use.



Avoid direct contact with skin and eyes. If contact occurs, wash affected area with copious amounts of water. Seek medical advice if irritation persists.

4.6 Adverse reactions (frequency and seriousness)

Acute reaction: Hypersensitivity reactions.

Chronic reaction: granulocytopenia, thrombocytopenia, liver damage, kidney damage and central neurotoxic reaction.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For oral administration:

Cattle and sheep: 20-25mg per kg of body weight, calculated as Sulfamethoxazole, equivalent to 1 bolus per 80-100kg body weight.

Dose stated is single dose, and can be repeated after 3 days if necessary.

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

Not applicable.

4.11 Withdrawal period(s)

- For meat: Cattle and sheep: 28 days

- For milk: 7 days

5 Pharmacological properties

Sulfadiazine (SDZ) inhibits the incorporation of para-aminobenzoic acid into folic acid and trimethoprim (TMP) inhibits the enzyme dihydrofolate reductase (DHFR) which converts dihydrofolic acid into tetrahydrofolic acid. (TMP) and SDZ act together synergistically with a double-blockade mode of action. The combination is bactericidal inhibiting sequential steps in the synthesis of purines which are required for DNA synthesis. TMP-SDZ combination has a broad and bactericidal action against many gram-positive and gram-negative aerobic bacteria, a large proportion of anaerobic bacteria, chlamydia, and protozoa.

ATCvet code: QJ01EW10



6. Pharmaceutical particulars

6.1 List of excipients

Sucrose

Dextrin

Talc

Magnesium Stearate

Tartrazine

Maize Starch

6.2 Incompatibilities

None known.

6.3 Shelf life

2 years.

6.4. Special precautions for storage

Store in a cool dry place below 30°C. Protected from light.

6.5 Nature and composition of immediate packaging

Box with 1 blister containing 4 boluses.

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

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