Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Sulphadimidine Sodium Powder for Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per g powder:
Sulphadimidine Sodium 1000 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution.
A white or creamy white odourless powder

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and poultry (non-laying hens and broilers).

4.2 Indications for use, specifying the target species

For the treatment of infections caused by micro-organisms (both bacteria and coccidia) susceptible to sulphadimidine.

4.3 Contraindications

Do not use in animals with serious liver and renal disturbances or in animals with diseases accompanied with a decreased intake of fluids or a decreased urine production, or in cases of aciduria.
Do not use in animals with damage to the haematopoietic system.
Do not administer to laying hens.
Do not use in cases of hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

After administration of this product to ruminants, sometimes a temporary interference with ruminal function and microfloral activity may occur. However, spontaneous recovery is likely.

4.5 Special precautions for use

Special precautions for use in animals
Monitor water intake in poultry and calves during treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Avoid skin contact with the powder and avoid inhalation of the dust.

4.6 Adverse reactions (frequency and seriousness)

Hypersensitivity reactions may occur, but are very rare in the target species.
Poultry, especially young birds, have shown a diminished water and feed intake and a retardation of growth after administration of sulfadimidine sodium via the drinking water.
Nephrotoxic disturbances may occur, depending on the dose and duration of administration (symptoms will be more pronounced in cases of decreased diuresis).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy, lactation or lay.
Use only according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Simultaneous administration with para-aminobenzoic acid, its esters (e.g. procaine, tetracaine) and methenamine must be avoided.
The combination of sulphadimidine with ionophore anticoccidials may cause an enhanced toxicity; little with lasolocid, more significant in combination with monensin especially at higher dosages of monensin (180 ppm or higher) resulting in a clear drop in water and feed intake and retarded growth. At normal concentrations these interactions are unlikely to occur.

4.9 Amounts to be administered and administration route

For oral administration via the drinking water.
Calves: 100 mg per kg bodyweight with a dosage interval of: 12-24 hours during 3-5 days.
Poultry (non laying hens and broilers): 100 mg per kg bodyweight corresponding to approximately 1 g powder per 1-2 litres of drinking water (depending on actual water intake).

In case of acute coccidiosis: Administration during 3 consecutive days; after 2 days of no treatment, another 3 day treatment.
In case of subclinical coccidiosis: Administration for 3 consecutive days.

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

Acute overdose:
Following an overdose a clear drop in water intake will occur in poultry. Administration to calves via the artificial milk may lead to a retarded uptake of water and to diarrhoea.

Chronic overdose:
Haemorrhagic symptoms have been reported after long term administration of sulphonamides. A certain degree of immunosuppression may occur making the animals more susceptible to secondary bacterial infections (especially gangrenous dermatitis in poultry). All mentioned side effects under 4.6 may also occur following chronic overdosing.

4.11 Withdrawal Period(s)

Cattle: Meat & offal: 21 days
Milk: 5 days (i.e. 11th milking)
Poultry: Meat & offal: 14 days
Do not administer to laying hens.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use; Sulfonamides; Sulfadimidine / Antiparasitic products, insecticides and repellents; Antiprotozoals; Sulfadimidine.
ATCvet Codes: QJ01EQ03 / QP51AG01.

5.1 Pharmacodynamic properties

Sulphonamides are corrective antagonists of para-aminobenzoic acid (PABA), and thus prevent normal bacterial utilisation of PABA for the synthesis of folic acid (bacteriostatic effect). Sulphadimidine inhibits not only bacteria but also protozoal agents such as coccidia. Sulphonamides act especially on the 2nd generation schizont. This stage is important for the development of natural immunity, so sulphonamides hardly influence development of natural immunity.

5.2 Pharmacokinetic properties

Sulphadimidine sodium is absorbed relatively rapid from the gut. In cattle the absorption half life is approximately 6 hours. Bioavailability depends on age and disease status (increased during diarrhoea) and ranges between 40 - 80%.

Concentrations in tissues are significantly lower than in plasma (except for kidneys), with relatively high concentrations in muscle and skin and lower levels in liver and fat (Vd. = 0.4 1 per kg bw).

Sulphadimidine is extensively metabolised and is eliminated with the urine, faeces and bile (and with the milk). However, the kidney is the organ primarily involved in the excretion of the drug.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

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 dilution or reconstitution according to directions: 24 hours

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

LDPE bags of 1kg, 5kg, 10kg, 25 kg and 50kg.
Sealed 4 layer sachet (clay-coated paper/polyethylene/aluminium foil/ionised) of 25g.

Not all pack sizes may be marketed

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

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

7 MARKETING AUTHORISATION HOLDER

Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10989/012/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1988

Date of last renewal: 30th September 2008

10 DATE OF REVISION OF THE TEXT

December 2016