Sulfadimidin 100% Powder

1000 mg/g, powder for oral administration

for cattle, sheep, goats, pigs, horses and dogs

Active ingredient: sulfadimidine

Name and address of the marketing authorisation holder:
bela-pharm GmbH & Co.KG
Lohner Str. 19
49377 Vechta / Germany

Name of the veterinary medicinal product:
Sulfadimidin 100% Powder
1000 mg/g, powder for oral administration for cattle, sheep, goats, pigs, horses and dogs.
Active ingredient: sulfadimidine

Statement of the active substance(s) and other ingredient(s):
1 g powder contains:
Pharmacological active substance:
Sulfadimidine 1000 mg
White Powder.

Indications:
In cattle, calves, sheeps, goats, pigs, piglets, horses, foals, and dogs for the treatment of the following diseases in the early stage of infection caused by germs sensitive to sulfonamides:
- septicaemia, bacteriaemia,
- secondary bacterial infections in viral infections,
- infections of the respiratory tract,
- infections of the gastro-intestinal tract,
- infections of the uro-genital tract,
- febrile metritis and mastitis,
- bacterial puerperal diseases,
- calf diphteroid (necrobacillosis),
- navel infections,
- infections of joints and claws,
- skin and wound infections,
- coccidiosis.

Contraindications:
Severe dysfunction of liver and kidney, diseases accompanied by reduced fluid intake or loss of fluid, aciduria, damage of the haematopoietic system, hypersensitivity to sulfonamides, resistance against sulfonamides.
Do not administer to mares, of which milk is gained for human consumption.

Adverse reactions:
- liver damage,
- kidney damage, with the following symptoms: haematuria, crystalluria, renal colic, inappetence, vesical tenesmus;
- allergic reactions,
- changes in the haemogram.

Following administration of high doses digestion disturbances may appear.
In cattle, an inhibition of the cellulose digestion has been observed.
The administration of sulfadimidine with the milk replacer to calves may lead to delayed intake of the milk and diarrhoea.
In cattle, sulfadimidine may induce a slight increase of leucocytes.
If any symptom described above is visible, stop treatment with Sulfadimidin 100% Powder immediately.
Countermeasures:
In signs of renal damage: give fluids and alkalize the urine.
In anaphylactic shock: epinephrine (adrenaline) and glucocorticoids i.v.
In weaners and piglets the incidence of a haemorrhagic syndrome with occurance of death after prolonged administration has been described. According to recent knowledge, the administration of vitamin K during treatment with sulfonamides in pigs can reduce the risk of the appearance of haemorrhagic syndrome. Keeping on slatted floor is a form of predisposing factor as the possibility of coprophagia and thereby the intake of vitamin K is reduced.

Target species:
Cattle, calf, sheep, goat, pig, piglet, horse, foal, dog.

Dosage for each species, route(s) and method of administration:
Powder for administration with the feed. For the treatment of single animals.
· *Cattle, calf, pig, piglet, horse, foal, dog:*
50 - 100 mg sulfadimidine / kg body weight (b.w.) daily, equivalent to
0.5 - 1 g Sulfadimidin 100% Powder per 10 kg b.w. per day.
Therapy shall be started with an intravenous injection of an initial dose of 100 mg/kg b.w. of a parenteral preparation and to be continued on the following 2 to 6 days with Sulfadimidin 100% Powder in the maintenace dose (50 - 65 mg/kg b.w.).

· *Sheep, goat:*
100 mg sulfadimidine / kg body weight (b.w.) daily, equivalent to
1 g Sulfadimidin 100% Powder per 10 kg b.w. per day.
Duration of treatment: 5 – 7 consecutive days.
Give the daily dose once daily or distribute to several even doses.
The appropriate quantity of powder is to be mixed into a small amount of feed fresh daily and is to be given prior to the actual feeding.
It has to be ensured that the entire dose is taken without residues.
Should there be no significant improvement of the pathological state after 3 days of treatment, review the diagnosis and change the therapy, if necessary. After cessation of clinical symptoms therapy should be continued for 2 more days.
In animals with clearly disturbed general state of health, the parenteral administration of a pharmaceutical shall be preferred.

Advice on correct administration:
See above (method of administration).

Withdrawal periods:

Cattle:	edible tissues:	12 days
	milk:	5 days
Goat:	edible tissues:	10 days
	milk:	5 days
Sheep:	edible tissues:	8 days
	milk:	3 days
Pig:	edible tissues:	12 days
Horse:	edible tissues:	10 days

Do not use in mares of which the milk is gained for human consumption.

Special storage precautions:

For this veterinary medicinal product no special storage conditions are required.
Shelf life after first opening the container: 7 days
Residuals of the pharmaceutical remaining in the container after the period to be used up is terminated are to be wasted.
Do not use after the expiration date stated on the label and the outer packaging.
Keep out of reach and sight of children.

Special warnings:

Special warnings for each target species
Not indicated.

Special precautions for use
Special precautions for use in animals
To prevent renal damage in dogs by crystalluria, ensure adequate water intake during treatment; possibly the urine shall be alkalized.
Ensure adequate water intake during treatment.
The use in pregnant and newborn animals requires strict indications.
The application of the veterinary medicinal product should be carried out taking into account a sensitivity test (antibiogram) and according to the official and local regulations for the use of antibiotics.
Application of the product deviating from this specification may increase the prevalence of sulfadimidine-resistant bacteria and reduce the effectiveness of treatment with sulfonamides due to potential cross-resistance.

Special safety precautions to be taken by the person administering the medicinal product to animals
Avoid direct skin contact and inhalation during handling and application due to the risk of sensitization or contact dermatitis. For this purpose, wear a dust mask and gloves.
Persons with known hypersensitivity to sulfonamides should avoid contact with the veterinary medicinal product.
If after contact a hypersensitivity reaction (e.g. reddening of the skin) occurs seek medical advice and refer to the leaflet or label. Swelling of the face, lips or eyes are more serious symptoms that require urgent medical attention.
Do not smoke, eat or drink during handling.

Use during pregnancy, lactation or lay
The secure use of sulfonamides during pregnancy is not proved. Sulfonamides shall only be administered when the advantages clearly exceed the risk of treatment.

Interaction with other medicinal products and other forms of interaction
Sulfadimidin 100% Powder must not be used concomitantly with hexamethylentetramine (methenamine) and /or phenylbutazone.

Overdose (symptoms, emergency procedures, antidotes), if necessary
In case of overdose, atactic movements, muscle jerks and -cramps as well as comateous conditions and liver damage may be observed. Application of Sulfadimidin 100% Powder has to be stopped immediately.
The neurotrop effects are to be treated symptomatically by administration of central sedating agents (as barbiturates).
In addition to the administration of vitamin K or folic acid, an increase of renal excretion of sulfonamides by means of alkalising media (e.g. sodum bicarbonate) is indicated.

Special precautions for the disposal of unused product or waste materials:
Remaining quantities shall be preferably given to pollutant collecting points. When wasted together with the general household waste, it has to be ensured that no misuse of the pharmaceutical is possible. Veterinary pharmaceuticals must not be wasted with waste water or sewage systems. Local regulations for the disposal of pharmaceuticals have to be observed.

Date on which the package leaflet was last approved:
27.04.2017

Other informations:
OP 1 x 1 kg folding box with inside lining;
OP 6 x 1 kg folding box with inside lining;
OP 12 x 1 kg folding box with inside lining;
OP 24 x 1 kg folding box with inside lining;
OP 1 x 2.5 kg Card-O-Seal bag;
BP 1 x (1 x 1 kg folding box with inside lining);
BP 6 x (1 x 1 kg folding box with inside lining);
BP 12 x (1 x 1 kg folding box with inside lining);
BP 24 (1 x 1 kg folding box with inside lining).
Not all pack sizes may be marketed.

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