Antastmon®

500/100 mg/g, powder for oral administration

Active ingredients: Sulfadiazin/Trimethoprim

Target species: Cattle (calves), pigs (weaners, piglets), horses (foals), sheep (lambs), goats (kids), dogs








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

Composition:
1.0 g powder contains:
Pharmacological active substances:

Sulfadiazine	500.0 mg
Trimethoprim	100.0 mg

Pharmaceutical form:
Powder for oral administration with the feed or the milk / milk substitute.
White to almost white powder.

Pharmacotherapeutic group:
Sulfonamide-Trimethoprim combination

Target species:
Cattle (*calves*), *pigs* (*weaners*, *piglets*), *horses* (*foals*), *sheep* (*lambs*), *goats* (*kids*), and *dogs*.

Indications for use:
Calves, *weaners*, *piglets*, *lambs*, *kids*, *foals* and *dogs*:
Treatment of diseases caused by germs susceptible to sulfadiazine and trimethoprim in an early stage of infection:
Primary and secondary infections of:
- the respiratory tract,
- gastro-intestinal tract,
- urogenital tract,
- skin and joints,
- eyes and ears.

Contraindications:
- severe hepatic and renal dysfunction;
- damage of the haematopoietic system;
- hypersensitivity to sulfonamides and trimethoprim;
- cataract;
- resistance to sulfonamides and trimethoprim;
- diseases with strongly reduced water intake or high losses of liquids.

Do not administer to ruminant animals.

Adverse reactions:
The following undesirable effects may occur following a treatment with Antastmon®:
- hepatic damage;
- renal damage, linked with haematuria and crystalluria, renal colic, inappetence, compulsive micturition;

- allergic reactions
- disorders of the haemogram (haemolytic anaemia, agranulocytosis)
- indigestion
- sensibilization (exanthema, fever)

A haemorrhagic syndrome with letal incidence has been described in *weaners* and *piglets* following a prolonged treatment. According to present knowledge, a simultaneous prophylactic supplementation with vitamin K during the treatment of *pigs* is advisable. Flatdeck keeping without litter as well as slatted floors inhibit coprophagia and thus the intake of vitamin K: These types of management present a predisposing factor.
On the incidence of adverse effects as described above, the medication is to be withdrawn immediately and symptomatic treatment must be initiated.
In the evidence of renal damage: watering and alkalinisation of the urine;
In the case of anaphylactic schock: epinephrine (adrenaline) and glucocorticoids, i.v.;
In the case of allergic skin reactions: antihistaminics or glucocorticoids.

Dosage for each species, route and method of administration:
For administration with the milk, milk substitute or feed in *calves*.
For administration with the feed in *weaners*, *piglets*, *lambs*, *kids*, *foals* and *dogs*.
For the treatment of single animals:
Calves, *foals*:
2 x 15 mg sulfadiazine-trimethoprim combination/kg body weight (b.w.)/day
equivalent to 2 x 1 g Antastmon® per 40 kg b.w. per day
given twice daily at intervals of 12 hours.
Weaners:
2 x 15 mg sulfadiazine-trimethoprim combination/kg body weight (b.w.)/day
equivalent to 2 x 0.5 g Antastmon® per 20 kg b.w. per day
given twice daily at intervals of 12 hours.
Piglets, *lambs*, *kids*:
2 x 15 mg sulfadiazine-trimethoprim combination/kg body weight (b.w.)/day
equivalent to 2 x 0.125 g Antastmon® per 5 kg b.w. per day
given twice daily at intervals of 12 hours.
Dogs:
1 x 30 mg sulfadiazine-trimethoprim combination/kg body weight (b.w.)/day
equivalent to 1 x 0.25 g Antastmon® per 5 kg b.w. per day
given once daily at intervals of 24 hours.

The doses given are related to the amount of entire active ingredient consisting of sulfadiazine and trimethoprim in the given relation 5 : 1 and are only valid for a present susceptibility of the causative germs against both single components.
It has to be ensured that the provided dose is taken in completely.
The intake of feed and drinking water can vary considerably between day and night time. Mix the powder freshly before each application into part of the feed or drinker (in case of milk replacer into the ready for use milk replacer), so that a good mixture is achieved. This mixture has to be given before regular feeding.
Duration of treatment is at least 3 days, better 5 days for *calves*, *weaners*, *piglets*, *lambs*, *kids* and *foals* and 3 - 6 consecutive days for *dogs*. The treatment of *dogs* may be exceptionally extended up to 14 days.

Following cessation of symptoms, the treatment with Antastmon® should be continued for at least two more days.
Should there be no significant improvement of the state of health after 3 days of treatment, the diagnosis has to be reviewed and therapy has to be changed, if necessary.
In animals with a clearly disturbed general condition and/or animals showing a lack of appetite, a preparation for parenteral administration shall be preferred.

Withdrawal period(s):
Weaner, *piglet*, *calf*, *lamb*, *kid* and *foal*:
Edible tissues: 10 days

Special warnings:
Special warnings for each target species:
On account of the resistance situation as it is generally the case with sulfonamides, one has to reckon with resistances in the whole range of action in connection with the application of sulfadiazine/trimethoprim. The resistance to one of both components cancels the synergistic effect of the combination which is important to the therapeutic result. The resistance to one sulfonamide always concerns the entire group of sulfonamides.
Special precautions for use:
Special precautions for use in animals:
Treatment with Antastmon® should be carried out considering a bacterial susceptibility testing.
The use in pregnant or newborn animals requires a strict indication.
To avoid kidney damage by crystallization, a sufficient water intake has to be ensured during therapy, the urine can be alkalized in cases.
Following long-term use in dogs a possible development of cataract must be taken into consideration.
Special safety precautions to be taken by the person administering the veterinary medicinal product to animals:
Avoid direct skin contact and inhalation due to the risk of sensitisation or contact dermatitis during handling and/or application. For this purpose, wear a dust mask and gloves.
Use during pregnancy, lactation or lay:
The use in pregnant or newborn animals requires a strict indication.
For sulfonamides, the safe use during gestation is not proved. They only should be used when the advantages of a treatment clearly exceed the possible risks.
Interaction with other medicinal products and other forms of interaction:
Antastmon shall not be used concomitantly with hexamethylentetramin (methenamine), phenylbutazone.
Overdose:
Following absorption of larger amounts of sulfonamides, atactic movements, muscle jerks and muscle cramps as well as comateous stages and liver damage have been observed. Stop the therapy with Antastmon® immediately.
The symptomatic treatment of neurotroph effects is done by administration of central sedative substances, e.g. of barbiturates.
In addition to the administration of vitamin K or folic acid, an increase of renal excretion of sulfonamide by means of alkalising substances (e.g. sodium bicarbonate) is indicated.

Incompatibilities:
Avoid mixing with other medicinal products due to the possible risk of incompatibilities.

Special storage precautions:
For this pharmaceutical no special storage conditions are required.
Keep out of reach and sight of children.
Stability of the medicated milk or milk substitute: 6 hours.
Solutions of the pharmaceutical in the milk or milk substitute must be prepared immediately prior to its use and must be fed instantly.
Shelf life after first opening of the container: 14 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.

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.

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For animal treatment only.

Available on prescription only!

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