Trioxin® Kompaktat

250/50 mg/g, granules for oral administration

for cattle, horses and pigs

Composition
1.0 g granules contains:
Active substances:
Sulfadimethoxine 250.0 mg
Trimethoprim 50.0 mg

White to almost white granules.

Prescription only
MAH-No.: 8718.00.01

Target species
Cattle, horse and pig

Indications for use
Treatment of infectious diseases caused by germs susceptible to sulfadimethoxine and trimethoprim in an early stage of infection:
Primary and secondary infections of:
- the respiratory tract,
- the gastro-intestinal tract,
- the urogenital tract.

Contraindications
Do not use in
- Aciduria;
- hypersensitivity to sulfonamides or trimethoprim;
- resistance to sulfonamides or trimethoprim;
- severe dysfunction of the liver and kidney;
- disturbances of the haematopoietic system;
- diseases accompanied by reduced intake of water or heavy loss of fluids.

Special warnings
Special warnings:
On account of the resistance situation as it is generally the case with sulfonamides, one has to reckon that resistances may occur in the whole range of action in connection with the application of sulfadimethoxine/trimethoprim. The resistance to one of both components cancels the synergistic effect of the combination which is important for the therapeutic success. The resistance to one sulfonamide always concerns the entire group of sulfonamides.

Special precautions for safe use in the target species:
Treatment with veterinary medicinal product should be carried out considering a bacterial susceptibility testing.
To avoid kidney damage by crystallization, a sufficient water intake has to be ensured during therapy, the urine can be alkalized in cases.

Special 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.

Pregnancy and lactation
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
Local anaesthetics of the group of paraaminobenzoic esters (procain, tetracain), may inhibit the effects of sulfonamides locally.

Overdose
In case of overdose, substance residues remaining in the stomach are to be removed with saline laxatives.
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. sodium bicarbonate) is indicated.

Major incompatibilities
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products .

Adverse events
Target species: Cattle, horse, pig

Rare (<1 animal / 1,000 animals treated, including isolated reports):	Haematuria [1] Crystalluria [1] Renal colic [1] Pollakiuria [1]
Undetermined frequency (cannot be estimated based on available data):	Digestive tract disorder [2] Allergic reaction [2,3] Blood count change [2] Nephropathy [2] Hepatopathy [2] Haemorrhage [4]

[1] Symptoms indicative of crystal precipitation may occur, particularly during prolonged treatment with sulphonamides: Treatment should be discontinued immediately and fluids, possibly with added sodium bicarbonate, should be administered.

[2] Particularly when high doses are administered

[3] If allergic reactions occur, the medicine should be discontinued immediately and treated symptomatically:
For anaphylactic shock reactions: epinephrine (adrenaline) and glucocorticoids i.v..
For allergic skin reactions: antihistamines and/or glucocorticoids.

[4] In pigs (young animals), deaths have been reported during prolonged treatment. Treatment should therefore be limited to the prescribed duration. Based on current knowledge, simultaneous prophylactic vitamin K supplementation is advisable in pigs during treatment. Flat-deck housing without bedding and fully slatted floors prevent coprophagia and thus the absorption of vitamin K; these types of housing are a predisposing factor.

If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian.

Dosage for each species, routes and method of administration

For administration with the feed.

20 mg sulfadimethoxine-trimethoprim combination/kg body weight (b.w.)/day equivalent to 66.7 mg of the veterinary medicinal product per kg body weight per day.

In mother sows, daily medication 3-4 days before and 2-3 days after the farrowing date.

The doses given are only valid for a present susceptibility of the causative germs against both single components.

Prior to each application, the necessary amount is to be given in a part of the feed in a way that a complete mixture is achieved. This mixture is to be given prior to the actual feeding.

It has to be ensured that the provided dose is taken in completely.

To ensure a uniform feed intake by all animals to be treated, sufficient feeding places have to be provided. In case of outdoor housing, the animals should be kept in the stable during the duration of treatment.

The treatment period is generally 3–7 days. After the symptoms of the disease have subsided, treatment should be continued for at least 2 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.

After treatment, the feeding troughs and faecal areas must be thoroughly cleaned.

The veterinary medicinal product should only be administered to individually fed animals or a small group of animals where intake by the individual animal can be effectively controlled.

Advice on correct administration

See section “Dosage for each species, routes and method of administration“.

Withdrawal periods

Edible tissues of

Cattle, horse and pig: 10 days

Milk of cows: 5 days

Do not use in mares, of which milk is intended for human consumption.

Special storage precautions
Keep out of reach and sight of children.
For this veterinary medicinal product no special storage conditions are required.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 14 days.
Shelf life after mixing into meal: use up immediately.
Any residual quantities of the veterinary medicinal product remaining in the container after the expiry date should be discarded.

Special precautions for disposal
Remaining quantities shall be preferably given to national collecting systems. 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. These measures should help to protect the environment. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

Classification of veterinary medicinal products
Veterinary medicinal product subject to prescription.

Marketing authorisation numbers and pack sizes
8718.00.01

OP 1 x 40 g, OP 7 x 40 g, OP 35 x 40 g, OP 1 x 1 kg, OP 6 x 1 kg, OP 12 x 1 kg, OP 24 x 1 kg, OP 1 x 2.5 kg, BP 7 x (1 x 40 g), BP 35 x (1 x 40 g), BP 6 x (1 x 1 kg), BP 12 x (1 x 1 kg), BP 24 x (1 x 1 kg).
Not all packaging sizes may be marketed.

Date on which the package leaflet was last revised
10/2025

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).