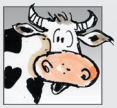
Trimetox® 240



Sulfadoxine 200 mg/ml
Trimethoprim 40 mg/ml

- Broad spectrum of activity through the combination of sulfadoxine and trimethoprim (sequential effect)
- Prolonged mode of effect through pharmacokinetically beneficial sulfonamide component

Trimethoprim-sulfonamide combinations continue to present valuable chemotherapeutic agents within veterinary medicine. A broader spectrum of pathogens is covered and the efficacy increased through the combination of both active substances.

A synergistic effect occurs. The combination has an antibacterial effect against numerous gram-positive and gram-negative bacteria (*E. coli*, Shigella species, Klebsiella species, *Proteus vulgaris*, Pasteurella species, Staphylococci, Streptococci, Pneumococci, Salmonellae, Acranobacterium species etc.) as well working as a coccidiostat against various Eimeria species (*E. tenella*, *E. necatrix*, *E. maxima*, *E. brunetti*, *E. acervulina* etc.) Compared to other sulfonamides, the sulfadoxine contained in Trimetox® 240 offers the advantage of a prolonged effect and from the pharmacological point of view is thus suited for the combination with trimethoprim.

The long-acting sulfadoxine counteracts the relatively short half-life of trimethoprim, thereby bridging those subtherapeutic treatment phases characterized by a lack of trimethoprim.

Trimetox® 240

200/40 mg/ml, injection solution for cattle and pigs
Active substances: Sulfadoxine, Trimethoprim

Active substances and other ingredients

Active substances:	
Sulfadoxine	200.0 mg/ml
Trimethoprim	40.0 mg/ml
Excipients:	
Methyl-4-hydroxybenzoate	0.5 mg/ml

Indications

For the treatment of infectious diseases in the early stage of the infection caused by sulfadoxine and trimethoprim susceptible pathogens:
Primary and secondary infections of the

– respiratory system,
– gastrointestinal tract,
– urogenital system,
– skin and joints.

Contraindications

Trimetox® 240 should not be used in case of

– hypersensitivity against sulfonamides or trimethoprim,
– resistance against sulfonamides or trimethoprim,
– severe liver and kidney function disorders,
– fluid losses,
– blood count disorders.

The intravenous application of Trimetox® 240 in case of a preceding or simultaneous application of substances that affect the central nervous system (e. g. anaesthetics, neuroleptics) should be avoided.

Adverse reactions
After use of Trimetox® 240 the following symptoms may occur

- Irritations at the injection site following intramuscular application,
- Liver damages,
- Kidney damages,
- Changes in the blood picture (e.g. haemolytic anaemia, agranulocytosis),
- Sensitising reactions (e.g. exanthemas, fever).

Following intravenous application in cattle, systemic reactions of short duration may occur (dyspnoea, excitation) in individual cases.
In case of the occurrence of allergic reactions the medicine should be discontinued immediately and symptomatically treated:
For anaphylaxis: epinephrine (adrenalin) and glucocorticoids i.v.
For allergic skin reactions: antihistamine and/or glucocorticoids.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

Target species
Cattle, pigs

Dosage for each species, routes and method of administration
For intravenous or intramuscular application.
25 mg sulfadoxine-trimethoprim combination/kg body weight (b.w.)/day,
equating to 1 ml injection solution/9.6 kg b.w./day
To ensure correct dosage and to prevent underdosage the body weight should be determined as accurately as possible. The recommended dosage should be applied in cases where pathogens exhibit sensitivity to both active ingredients.

Cattle, calves: For intravenous or intramuscular application.
Pigs, piglets: For intramuscular application.

Advice:
Because of the tissue irritating characteristics of Trimetox® 240, larger injection volumes administered intramuscularly in cattle should be given at different injection sites.
The treatment duration should at least cover 3 days, however, better 5 – 7 days. Following the subsidence of the disease symptoms Trimetox® 240 should be given for at least 2 further days.
Should there be no significant improvement in the state of the disease following one day of treatment, then it is advised that the treatment should only continue on the basis of an antibiogram; where applicable a change in therapy may be required.

Advice on correct administration
Maximum injection volume per injection site: 10 ml in cattle.
Further details see "Special warnings".

Withdrawal period

Intravenous:	Cattle:	meat and offal	6 days
		milk	4 days
Intramuscular:	Cattle:	meat and offal	6 days
		milk	4 days
	Pigs:	meat and offal	6 days

Special storage precautions
Keep out of the reach and sight of children.

Do not use after the expiry date stated on the label and the outer carton.

Keep the bottle in the outer carton and protect from light.
Shelf life after first opening the container: 28 days.
After the expiry of this period the remainder of the drug in the container is to be disposed of.

Special warnings

Special warnings for each target species
None.

Special precautions for use in animals
The application of Trimetox® 240 should be subject to an antibiogram.
In neonates, Trimetox® 240 should be used under strict indication only.
To avoid kidney damages caused by crystalluria an adequate fluid intake during the therapy is required. The urine may possibly be alkalized.
Cattle: Life-threatening shock reactions may occur as a consequence of the propylene glycol content. Therefore, the injection solution should be administered slowly and should be close to body temperature. The injection should be stopped at the first sign for intolerance, if required shock treatment should be initiated.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Due to the risk of sensitization, direct contact with the user's skin or mucous membranes should be avoided.

Use during pregnancy, lactation or lay
The safety of the administration of sulfonamides during pregnancy has not been verified. They should only be used when the benefit of treatment is significantly higher than possible risks.

Interaction with other medicinal products and other forms of interaction
Trimetox® 240 should not be co-medicated to
- hexamethylentetramine (methenamine),
- phenylbutazone,
- local anaesthetics from the paraaminobenzoic acid ester group (procaine, tetracaine), as they may locally reverse the effects of sulfadoxine.

Overdose (symptoms, emergency procedures, antidotes), if necessary
Following the absorption of high levels of sulfonamides, atactic movements, muscular twitching and spasms, along with comatose conditions and liver damages are primarily observed. For symptomatic treatment of the neurotropic effects central sedating substances, e.g. barbiturates should be administered.

In addition to vitamin K or folic acid treatment, an increase of the renal excretion of sulfonamides is achieved using alkalizing substances (e.g. sodium carbonate).

Incompatibilities
Intravenous application of Trimetox® 240 in case of a preceding or simultaneous application of substances that affect the central nervous system (e. g. anaesthetics, neuroleptics) should be avoided.

Special precautions for the disposal of unused product or waste materials, if any:

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements. Ask your veterinary surgeon how to dispose of medicines no longer required.

To be applied only on veterinary prescription.

Package sizes

100 ml bottle
250 ml bottle

The information given in this product brochure conforms to the state of knowledge on completion. Please read the package leaflet before using the veterinary medicinal product.

The provisions of a national marketing authorisation, which may be different from the details given in this brochure, are binding.

Veyx-Pharma is GMP- and QS-certified.

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