Trimetox® 240

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Injection solution for cattle and pigs

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT
Veyx-Pharma GmbH
Soehreweg 6
34639 Schwarzenborn
Germany

NAME OF THE VETERINARY MEDICINAL PRODUCT
Trimetox® 240 200/40 mg/ml
Injection solution for cattle and pigs
Active substances: Sulfadoxine, Trimethoprim

STATEMENT OF THE 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, ROUTE(S) 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 exhibitsensitivity 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 PERIODS

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 WARNING(S)
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.

Int*eraction 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.

OTHER INFORMATION
Package sizes:
100 ml bottle
250 ml bottle

Not all package sizes may be marketed.