

Sulphix®

200/40 mg/ml, solution for injection

for cattle, goats, horses, pigs, cats and guinea pigs

Composition

1 ml contains:

Active substance:

Trimethoprim 40.0 mg

Sulfadoxine 200.0 mg

Excipients:

Glycerol formal, Sodium hydroxide, Water for injection

Clear, yellowish, brownish or reddish solution for injection.

Available on prescription only!

MA-No: 6856907.00.00



Target species

Cattle, goat, horse, pig, cat, guinea pig.

Indication for use

For the treatment of infectious diseases in the early stage of infection, caused by bacteria sensitive to sulfadoxine and trimethoprim. Primary and secondary infections

- of the respiratory tract,
- of the gastro-intestinal tract,
- of the urinary and genital tract,
- of the joints.

Contraindications

Do not use in

- hypersensitivity against sulfonamides or trimethoprim,
- resistance against sulfonamides or trimethoprim,
- severe hepatic and renal malfunctions,
- dehydration,
- disturbances of the haemogram.

Due to the contents of glycerolformal, Sulphix should not be used in pregnant animals.

The intravenous injection of Sulphix shall be avoided when drugs acting on the central nervous system (e.g. anaesthetics, neuroleptics) have been applied.

Special warnings

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In the horse life-threatening anaphylactic or anaphylactoid reactions may occur following intravenous injection.

When using the same way of administration in sedated or anaesthetized horses severe circulatory failures with incidents of death have been described.

Special precautions for safe use in the target species:

To avoid kidney damage by crystallization, a sufficient water intake has to be ensured during therapy, the urine can be alkalinized in cases.

The use in newborn animals requires a strict indication.

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 sulfadoxin and / or trimethoprim-resistant bacteria and reduce the effectiveness of treatment with sulfonamides and / or trimethoprim due to potential cross-resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The direct contact with the skin or mucous membranes of the user must be avoided due to the risk of sensitization. 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.

Pregnancy and lactation:

Due to its glycerolformal contents, the veterinary medicinal product must not be used in pregnant animals.

For sulfonamides, the safe use during gestation is not proved. They should only be used, when the advantage of a treatment clearly exceeds the risks.

Interaction with other medicinal products and other interaction

Sulphix must not be used concomitantly with

- hexamethylentetramin (methenamine),
- phenylbutazone,
- local anaesthetics of the group of para-amino benzoic acid esters (procaine, tetracaine), as they may cancel out the effect of sulfadoxine locally.

Overdose:

Following absorption of larger amounts of sulfonamides, atactic movements, muscle jerks and muscle cramps as well as comatose stages and liver damage have been observed. The symptomatic treatment of neurotroph effects is done by administration of central sedative substances, e.g. of barbiturates. Additionally to an administration of vitamin K or folic acid, an increase of renal excretion by application of alkalisng substances (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

Cattle, goat, horse, pig, cat, guinea pig:

Uncommon (1 to 10 animals / 1,000 animals treated):	irritation at the injection site ¹ liver damage, renal damage, changes in the haemogram (e.g. haemolytic anaemia, agranulocytosis), sensibilisation reactions (e.g. exanthema, fever)
Undetermined frequency (cannot be estimated based on available data):	Dyspnoea, excitation ² anaphylactic shock, anaphylactoid reaction ³

¹ after intramuscular or subcutaneous injection

² short-lived systemic reactions after intravenous application in cattle

³ after intravenous injection in horses, life-threatening.

On the occurrence of allergic reactions, the drug has to be withdrawn immediately and the animal must be treated symptomatically.

In anaphylaxis: epinephrine (adrenalin) and corticosteroids i.v.

In allergic skin reactions: antihistaminics and/or glucocorticoids

Dosage for each animal species, routes and method of administration

- Intravenous use: horses, cattle, pigs, goats, cats.
- Intramuscular use: cattle, pigs, goats, cats.
- Subcutaneous use: cats.

15 mg sulfadoxine-trimethoprim combination / kg body weight (b.w.) per day, equivalent to 1 ml Sulphix per 16 kg b.w. per day.

The doses mentioned are related to the amount of the entire active ingredient, consisting of sulfadoxine and trimethoprim in the relation of 5:1 and is only valid for germs sensitive to both single components.

Remarks:

Following intravenous injection in horses life-threatening shock reactions may occur. This way of application shall be used in this animal species only in vital indications and in form of an injection of a small amount of the preparation with consequent observation of the patient and a slow injection of the main portion. The solution injected should have body temperature. On the first signs of intolerance, the injection has to be stopped immediately and a treatment of shock shall be initiated, if necessary.

Due to the tissue irritating effect of the veterinary medicinal product, larger volumes of injection given by intramuscular injection in cattle shall be distributed to several injection spots.

Guinea pigs:

For subcutaneous or intramuscular injection:

24 mg sulfadoxine-trimethoprim combination / kg body weight (b.w.) per day, corresponding to 0.1 ml of the veterinary medicinal product per kg b.w. per day.

Horses, cattle, pigs, goats, cats, guinea pigs:

The duration of treatment is at least 3 days, better 5 days.

In order to ensure correct dosage, the body weight should be determined as accurately as possible.

After cessation of symptoms, the treatment with Sulphix shall be continued for two more days.

Should there be no significant improvement of the state of health after the first day of treatment, the treatment should only be continued, if an antibiogram has clearly demonstrated the sensitivity of the causative germ, if necessary a change of therapy has to be initiated.

Withdrawal periods

Following intravenous injection:

Cattle, goat:	edible tissues:	4 days
	milk:	4 days
Pig:	edible tissues:	5 days
Horse:	edible tissues:	4 days

Following intramuscular injection:

Cattle, goat : edible tissues: 11 days
 milk: 4 days

Pig: edible tissues: 14 days

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

Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Any residues of the medicinal product remaining in the container must be discarded after the expiry date after opening.

Shelf life after first opening the immediate packaging: 7 days

Special precautions for disposal

Unused veterinary medicinal products should preferably be disposed of at hazardous waste collection centres. If disposed of together with household waste, it must be ensured that this waste cannot be misused. Veterinary medicinal products must not be disposed of with waste water or via the sewage system. These measures serve to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines that are no longer needed.

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

Pack sizes

100 ml clear glass vial type II with bromobutyl rubber stopper and flanged aluminium cap

250 ml clear glass vial type II with bromobutyl rubber stopper and flanged aluminium cap

OP (1 x 100 ml); OP (6 x 100 ml); OP (12 x 100 ml); OP (1 x 250 ml); OP (6 x 250 ml);

OP (12 x 250 ml); BP 6 x (1 x 100 ml); BP 12 x (1 x 100 ml); BP 8 x (6 x 100 ml);

BP 4 x (12 x 100 ml); BP 6 x (1 x 250 ml); BP 12 x (1 x 250 ml); BP 8 x (6 x 250 ml);

BP 4 x (12 x 250 ml).

Not all pack sizes may be marketed.

Date on which the package leaflet was last revised

01/2025

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