Sulphix

200/40 mg/ml, solution for injection

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

Active ingredients: Trimethoprim, Sulfadoxine

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

Name of the veterinary medicinal product:
Sulphix, 200/40 mg/ml, solution for injection
for cattle, goats, horses, pigs, cats and guinea pigs.
Active ingredients: Trimethoprim, Sulfadoxine

Statement of the active substance(s) and other ingredient(s):
1.0 ml solution contains:
Pharmacological active substance:
Trimethoprim 40.0 mg
Sulfadoxine 200.0 mg
Clear, yellowish, brownish or reddish solution for injection.

Indications:
Horse, cattle, pig, goat, cat, guinea pig.
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,

and the joints.

Contraindications:
- hypersensitivity against sulfonamides or trimethoprim,
- resistance against sulfonamides or trimethoprim,
- severe hepatic and renal malfunctions,
- dehydration,

and 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.
Do not use in newborn animals.
Do not use in mares, of which the milk is intended for human consumption.

Adverse reactions:
Following administration of Sulphix, the following undesirable effects may occasionally occur:
- symptoms of irritation of the injection site after intramuscular or subcutaneous injection,
- liver damage,
- renal damage,

- changes in the haemogram (e.g. haemolytic anaemia, agranulocytosis),
- sensibilisation reactions (e.g. exanthema, fever).

Following intravenous injection cattle may show systemic reactions (dyspnoe, excitation) for a short time.
In the horse life threatening anaphylactic or anaphylactoid reactions may occur after intravenous injection.
On the occurence of allergic reactions, the drug has to be withdrawn immediately and the animal must be treated symptomatically.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

Target species:
Horse, cattle, pig, goat, cat, guinea pig.

Dosage for each species, route(s) and method of administration:

· *Horses, cattle, pigs, goats, and cats.*
For intramuscular, intravenous, or subcutaneous injection.
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.
Intravenous use in: horses, cattle, pigs, goats, cats.
Subcutaneous use in: cats.
Intramuscular use in: cattle, pigs, goats, cats.
Remarks:
Following intravenous injection in horses life-threatening shock reactions may occur. This way of application shall by 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 intolerability, the injection has to be stopped immediately and a treatment of shock shall be initiated, if necessary.
Due to the tissue irritating effect of Sulphix, 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 Sulphix 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 and to avoid underdose, 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 1 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.

Advice on correct administration:
See above (method of administration).

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:
Shelf life after first opening the container: 7 days
Residuals of the pharmaceutical remaining in the container after the period to be used up is terminated are to be wasted.
Keep out of reach and sight of children.

Special warnings:
Special warnings for each target species
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 use:
Special precautions for use in animals:
To avoid kidney damage by crystallization, a sufficient water intake has to be ensured during therapy, the urine can be alkalized 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.

Use during pregnancy, lactation or lay:
Due to its contents of glycerolformal, Sulphix 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.
Mares, of which milk is taken for human consumption, must be excluded from treatment.

Interaction with other medicinal products and other forms of 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 (symptoms, emergency procedures, antidotes):
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. The symptomatic treatment of neurotroph effects is done by administration of central sedative substances, e.g. of barbiturates. Additonally to an administration of vitamin K or folic acid, an increase of renal excretion by application of alkalising substances (e.g. sodium bicarbonate) is indicated.

Incompatibilities:
Mixtures with other medicinal products must be avoided due to a risk of possible incompatibilities.

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.

Date on which the package leaflet was last approved:
27.07.2017

Other informations:
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.