

Vitamin E + Selen

100 mg/ml / 2 mg/ml, emulsion for injection
in horses, cattle, pigs, sheep, goats, dogs and cats

Name and address of the marketing authorisation holder:

Bela-Pharm GmbH & Co. KG
Lohner Straße 19
D-49377 Vechta/ Germany

Name of the veterinary medicinal product:

Vitamin E + Selen
100 mg/ml / 2 mg/ml, , emulsion for injection in horses, cattle, pigs, sheep, goats, dogs,
and cats

Statement of the active substance(s) and other ingredient(s):

1.0 ml emulsion contains:

Pharmacological active substance:

all-rac alpha-tocopherol acetate	100.0 mg
Sodium selenite	2.0 mg

Adjuvants:

Benzyl alcohol	20.0 mg
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Emulsion for injection.

Cloudy to milky-white /yellowish emulsion.

Indications:

Horse, cattle, pig, sheep, goat, dog, and cat.

Therapy of vitamin E deficiency diseases and for substitution at increased demands, especially: muscle dystrophy, myopathy, and mulberry heart disease. A treatment with Vitamin E + Selen pro injectione is only promising in the early stage of illness or for prophylaxis.

Contraindications:

Do not use in known hypersensitivity to all-rac alpha-tocopherol acetate or sodium selenite or any other ingredient of the veterinary medicinal product.

Adverse reactions:

Fattening pigs weighing between 60 and 90 kg may show low tolerance.

In cattle and horses systemic reactions up to anaphylactic shock and death may occur.

Following intramuscular injection severe reactions at the injection site may be observed.

Target species:

Horse, cattle, pig, sheep, goat, dog and cat.



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

For single subcutaneous injection:

<i>Horse and cattle:</i>	5 - 10 ml / animal
<i>Calf:</i>	2 - 4 ml / animal
<i>Sheep, goat:</i>	1 - 1.5 ml / animal
<i>Pig:</i>	3 ml / animal
<i>Weaner:</i>	2 ml / animal
<i>Dog, cat:</i>	0.5 - 1 ml / animal

Advice on correct administration:

Not indicated.

Withdrawal periods:

<i>Horses:</i>	Edible tissues:	7 days
	Milk:	0 days
<i>Cattle:</i>	Edible tissues:	7 days
	Milk:	0 days
<i>Pigs:</i>	Edible tissues:	7 days
<i>Sheep, goat:</i>	Edible tissues:	7 days
	Milk:	0 days

Special storage precautions:

Store in a refrigerator (2 °C - 8 °C).

Keep out of the sight and reach of children.

Shelf life after opening: 28 days.

Special warnings:

Special warnings for each target species:

None.

Special precautions for use:

Special precautions for use in animals:

The veterinary medicinal product Vitamin E + Selenium may not be used on infants during the first week of life because of its content of benzyl alcohol.

Do not administer more than the recommended dose. In cats, due to the risk of liver damage, it should be ensured that the dose administered does not reach or exceed 10 mg benzyl alcohol / kg body weight.

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

Wash hands after use.

Alpha-tocopherol acetate and sodium selenite can cause hypersensitivity.

Persons with known hypersensitivity to alpha-tocopherol acetate or sodium selenite should avoid contact with the veterinary medicinal product.

If symptoms of rash develop following accidental exposure, seek medical advice and show the package leaflet or label to the physician. Swelling of the face, lips or eyelids or difficulty breathing are serious and need urgent medical attention.

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The veterinary medicinal product may be irritating to the skin. Contact with the skin should be avoided. In case of accidental contact wash skin immediately with soap and water.

The veterinary medicinal product may be eye irritant. Contact with the eyes should be avoided. In case of accidental contact, rinse eyes with plenty of water.

The veterinary medicinal product may cause reactions at the injection site. To avoid accidental self-injection, use should be done with care. In case of accidental self-injection seek medical advice immediately and show the package leaflet or label.

Use during pregnancy or lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose (symptoms, emergency procedures, antidotes):

Because of a relatively high toxic potential of selenium, the doses recommended must be strictly observed. Symptoms of an acute overdosage are unspecific, as inappetence, salivation and nausea.

In chronic selenium toxicosis alopecia, hoof and claw deformations with partial detachment of the hoof wall, and damage on the articular cartilage may be observed. In such cases application of preparations containing selenium must be stopped immediately.

Incompatibilities:

None known.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed in accordance with local requirements.

Date on which the package leaflet was last approved:

11.11.2020

Other informations:

1 x 100 ml

6 x 100 ml

12 x 100 ml

Not all pack sizes may be marketed.

Marketing authorisation number: 402288.00.00 (Germany)

For animal treatment only.

Available on prescription only!