SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Selen E-sol forte – emulsion for injection for animals

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substances:

DL-α–Tocopherolacetate (Vit. E)	150.0 mg
Selenium (as Sodium Selenite)	0.5 mg

Excipients: Benzyl alcohol 10 mg, Phenol 5 mg

Other ingredients:
For a full list of excipients please see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection

4. CLINICAL PARTICULARS

4.1 Target species

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

4.2 Indications for use, specifying the target species

Subclinical and clinical diseases if primary and secondary caused by a vitamin E – selenium deficiency:

Diseases of the heart- and skeletal musculature of nutritional origin like locomotor disorders, trembling, paralysis, degenerations, splayleg, tachicardia, cyanosis, transport stress, loss of appetite.
Reproductive disorders (degeneration of the testes, involutional processes of the ovaries), Degeneration of the embryo (resorption of the foetus, weakness of the newly born).

Calf, lamb:
White muscle disease, exudative diathesis, enzootic muscular dystrophy, liver-necrosis.

Pigs:
Enzootic heart death, degeneration of the myocardium, mulberry heart disease, ('Yellow fat') - cod-liver-oil and soy-disease, necrosis of muscular tissue, iron sensitiveness.

Horses:
Dietetic myopathy, myositis, performance impairment.

Nutritional muscular diseases in young animals occur relatively frequent. A systematic treatment of all calves, young bulls, lambs and piglets in suckling-, weaning- and fattening-peroid or 2 - 3 weeks before being put out to pasture (e.g. at one go with vaccinations) is appropriate.

4.3 Contraindications

Do not use in case of known hypersensitivity to the active ingredients, adjuvants or to any of the excipients.
Due to the content of benzyl alcohol do not use in newborn animals during the first few weeks and do not administer to cats of any age.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
In case of contemporary administration of products containing Selenium (also foodstuff) take care that the total amount of Selenium will not be too high.

Special precautions to be taken by the person administering the veterinary medicinal product to animal
In case of accidential self-injection seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

If used properly, no adverse reactions are to be expected.
Possible local muscle pain of short duration is attributable to intra-muscular application.
In very rare and special cases (sensibilisation or predisposition of unknown origin), the occurrence of allergic or so-called pseudo-allergic reactions, especially in horses and cattle cannot be ruled out. These can progress differently both in time and extent (drop in blood pressure, circulatory disturbances, dyspnoea, heat accumulation). If necessary, suitable symptomatic measures (antihistamines, glucocorticoids, circulatory agents) should be initiated.
Further adverse reactions may eventually occur if the total amount of Selenium substitution is too high. Please see point 4.5 and 4.10.

4.7 Use during pregnancy and lactation

Can be used during pregnancy and lactation. As selenium passes the placenta and is excreted in the milk, it is good practice to treat the pregnant animals during the last third of the pregnancy period as a preventative measure, so that the foeti will be supplied with a sufficient amount in the womb or through the breast milk.

4.8 Interactions with other medicinal products and other forms of interactions

Vitamin E can be used to increase the Retinol-absorption and metabolism of Vitamin A.
High doses of Vitamin E may delay the haematological response of an iron therapy in animals with iron deficiency anaemia.

4.9 Amounts to be administered and administration route

Preferably subcutaneously, also intramuscularly.

Horses, cattle	10 ml	Piglets	1 – 2 ml
Foals, calves	5 ml	Sheep, goats	5 ml
Fattening pigs, sows	5 – 10 ml	Lambs, kid goats	2 – 3 ml
Weaners	2 – 4 ml	Dogs	0.2 – 1 ml

In severe cases treatment can be repeated in weekly intervals.
Metaphylactically application every 3 months is sufficient.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

The essential trace element Selenium leads to intoxications in higher doses.
If symptoms of a Selenium overdosage appear (disturbances of the nervous system, ataxias, dyspnoea, impaired vision, diarrhoea, muscle weakness and a garlicky smell of the breath - in horses also the loss of long hair and increased brittleness of the horn, respectively anorexia and vomiting in dogs), discontinue immediately the treatment with the preparation.

4.11 Withdrawal period

Zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutical group: other minerals, Selenium in combination;
ATCvet-code: QA12CE99

5.1 Pharmacodynamic properties

Selenium and Vitamin E fulfil essential biological functions in all cells and tissues of the organism. Both substances are complementary to one another due to their synergistic, anti-oxidative effect, by influencing the cell metabolism in two consecutive steps.

Selenium is an essential active ingredient, which physiological function is closely bound up with the function of Vitamin E and the sulfur-containing amino acids. While Vitamin E inhibits the formation of cell damaging peroxides, the glutathione-peroxidase – acting with Selenium as co-factor – decomposes the toxic peroxides, produced by the fatty acids.
In the same way it reduces the toxic hydrogen peroxide, which is produced by marginal Vitamin E supply in the organism, to non-toxic hydroxy fatty acids.

The physiological functions of Vitamin E in the organism are versatile. It has a regulating effect on the hypothalamus-hypophysis-system, supports the production of gonadotropines as well as

thyrothropin and adrenocorticotropic hormones. In addition Vitamin E has a specific effect on the maintenance of testis function and prevents the resorption of fetuses as it occurs due to the Vitamin E deficiency as well as liver necrosis. As a physiological antioxidant Vitamin E prevents by stabilisation of fatty acids, the formation of toxic lipoperoxide. Furthermore it improves the Vitamin A supply of the organism by protecting it from oxidative decomposition, supports the capillary function and increases the resistance of erythrocytic membrane.

5.2 Pharmacokinetic particulars

The major part of the plasma Selenium is bound to protein, it is accumulated under assistance of specific Selenium proteins. Selenium succumb an enterohepatic circulation. Selenite is primary excreted via the faeces and urine. An elimination via the lung and the skin is also possible.
After assimilation Vitamin E is accumulated in the whole organism, preferably in the liver and in the adipose tissue. It is eliminated via the bile.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogolglycerol Ricinoleate, Water for Injection.

6.2 Incompatibilities

There are no compatibility studies available, therefore this emulsion for injection must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packed for sale: 3 years
Shelf-life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

There are no special temperature storage conditions.
Store the vial in the carton box in order to protect from light.
After first opening do not store above 25°C.

6.5 Nature and composition of immediate packaging

Brown glass vial for 100 ml, glass type II, Ph.Eur. with rubber closure and alu cap.
Pack size: 5 x 100 ml

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

April 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

PRESCRIPTION/SELLING:
Available only on prescription and dispensed only in pharmacies.