

VITA E SELEN injection solution

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer:

Bioveta, a. s.,
Komenského 212,
683 23 Ivanovice na Hané,
CZECH REPUBLIC

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

VITA E SELEN injection solution

3. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml of slightly opalescent injection solution contains:

Active substances:

Tocoferoli alfa acetat 25 mg
Natrii selenis 2.2 mg
(equivalent to 1 mg of selenium)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Single-dose intramuscular administration to the neck muscle.

Animal species	Dose – prophylactic	Dose – therapeutic
Lambs up to 3 weeks of age	1 ml	2 ml
Lambs up to 3 weeks of age	2 ml	4 ml
Calves, young cattle	10 ml / 100 kg live weight	20 ml / 100 kg live weight
Piglets	1 ml / 10 kg live weight	2 ml / 10 kg live weight
Cows (3 weeks before calving)	20 ml	

General dose for young livestock (lamb, calf, young cattle, piglet):
Prophylactically 0.1 ml of the product/kg live weight, i.e. 2.5 mg of vitamin E and 0.22 mg of sodium selenite; therapeutically 0.2 ml of the product/kg live weight, i.e. 5 mg of vitamin E and 0.44 mg of sodium selenite.

General dose for cows:
0.04 ml of the product/kg live weight, i.e. 1 mg of vitamin E and 0.088 mg of selenite.
Large volumes should be applied into several sites.

9. ADVICE ON CORRECT ADMINISTRATION

The stopper can be punctured up to 50 times.

Excipients:

Benzyl alcohol (E1519) 20 mg
Disodium edetate dihydrate 0.221 mg

4. INDICATION(S)

Prevention and therapy of diseases associated with deficiency of vitamin E and selenium, especially muscular dystrophy in young livestock; beneficial effect on cow reproduction.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active ingredient or to any of the excipients.

6. ADVERSE REACTIONS

It is possible to develop anaphylactic shock, particularly in horses. If allergic signs occur, it is necessary to administer an antihistamine drug, possibly injection calcium product.

7. TARGET SPECIES

Lambs, calves, young cattle, cows, piglets.

10. WITHDRAWAL PERIOD

Meat: 30 days.
Milk: no withdrawal periods.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach of children.

Do not store above 25 °C.

Do not freeze.

Protect from light.

Do not use this veterinary medicine after its expiry date stated on the label and package. Shelf life after first opening the immediate packaging: 28 days.

12. SPECIAL WARNINGS

Special precautions for use in animals

Before administration it is necessary to check previous therapy (products containing selenium, feed ration supplements, licks containing selenium, etc.) to avoid accumulation of selenium. Before mass application it is necessary to perform tolerance test in 20% of the animals from the herd.

Period of observation is 24 hours.

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

Do not smoke, drink or eat while handling the product.

Avoid direct contact with skin, eyes and mucous membranes.

After contact with skin wash immediately the affected site under running water and take off contaminated clothing which is in contact with skin.

When handling the veterinary medicinal product, particularly in case of repeated administration (e.g. on factory farms), personal protective equipment consisting of protective gloves should be used.

In case of contact with eyes, rinse with plenty of drinking water.

If health problems arise, seek medical attention and show the package leaflet or label.

Accidental self-injection may cause anaphylactic reaction. Anaphylactic reactions, some of which may be fatal, have been reported in animals injected with vitamin E and selenium.

People with known hypersensitivity to sodium selenite (or other salts), vitamin E or any of the excipients (see section 6.1) should avoid contact with the veterinary medicinal product.

Avoid accidental self-injection.

In case of accidental self-injection, seek medical advice immediately and show the package insert or the label to the general practitioner.

The veterinary medicinal product should not be administered by pregnant women.

Use during pregnancy and lactation

Administration of the product during pregnancy and lactation is possible.

Interaction with other medicinal products and other forms of interaction

Simultaneous administration of selenium and amino acids (Met, Cys, L-Lys), vitamin C and vitamin E has a protective effect.

Overdose (symptoms, emergency procedures, antidotes):

Due to the potential risk of selenium toxicity, the exact dosage should be followed. No specific antidote has been determined.

If allergic signs occur, it is necessary to administer an antihistamine drug, possibly injection calcium product.

Incompatibilities

None known.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2014

15. MORE INFORMATION

For animal treatment only.

To be supplied only on veterinary prescription.

Not all pack sizes may be marketed.

For additional detailed information regarding this veterinary medical product, please contact your local representative of the marketing authorisation holder.



Dimensions (mm): A6 (105 × 148 mm) duplex printing
Colours: black
Prepared by: Vlková
Date: 19. 8. 2015

Approved by:

Date: