SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vitenium Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients:	%w/v
dl-alpha-tocopheryl acetate	15.0
Selenium (as anhydrous sodium selenite)	0.05

Other ingredients:

Antimicrobial preservative:

Benzyl alcohol	0.73
Methyl hydroxybenzoate	0.18
Propyl hydroxybenzoate	0.09
Other excipients to volume	100.0

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Opalescent yellow aqueous solution.

4. CLINICAL PARTICULARS

4.1 Target species

Horses, cattle and sheep.

4.2 Indications for use, specifying the target species

Prophylactic indications

a On farms in known selenium-deficient soil areas.

b When diets low in vitamin E are fed, e.g. diets containing high levels of moist stored grain or maize silage.

c On farms where there is a history of vitamin E and/or selenium deficiency, as may be indicated by poor breeding performance, excessive transport stress, or nutritional muscular dystrophy (in young animals on turning out to grass).

d To provide extra vitamin E during periods of heavy work-load (horses).

Therapeutic indications

For the treatment of the various manifestations of nutritional muscular dystrophy (white muscle disease, nutritional myopathy) affecting cardiac and/or skeletal muscles, and associated symptoms.

4.3 Contraindications

Do not overdose.

4.4 Special warnings for each target species

See Section 4.7 for warnings regarding use in pregnant cattle.
Administer to horses by intramuscular injection only.

4.5 Special precautions for use

i) Special precautions for use in animals

Do not overdose.

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

Care should be taken to avoid accidental self injection.

4.6 Adverse reactions (frequency and seriousness)

Anaphylactic type reactions have occasionally been reported following use of this product. In such an event, symptomatic treatment should be undertaken as appropriate.

4.7 Use during pregnancy, lactation or lay

Chronic administration of selenium has been shown to cause adverse fertility and foetal effects, but at the proposed frequency of dosing, i.e. every 1 – 12 weeks, these are not considered relevant. Anaphylactic type reactions have been reported in pregnant cattle treated with Vitenium Injection.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Shake bottle before use. Observe aseptic precautions.

For administration by intramuscular or subcutaneous injection in cattle and sheep, and by intramuscular injection in the horse.

The following should be used as a guide.

Adult animals

Prophylaxis	1 ml per 50 kg liveweight One injection at intervals of 3 months.
Treatment	1 ml per 30 kg liveweight Injections may be repeated at weekly intervals if necessary.
Horses	Up to 20 ml
Cattle	Up to 15 ml
Sheep	Up to 5 ml

Young animals

Foals, calves	2 – 5 ml
Lambs	0.5 – 3.0 ml

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

This product contains selenium and must not be overdosed. Overdosage should be treated as selenium poisoning. Chronic selenium poisoning is characterised by dullness and lack of vitality, emaciation and roughness of coat, loss of hair from mane and tail of horses, slowness and sloughing of hooves, stiffness and lameness due to joint erosion in the long bones, atrophy of the heart, cirrhosis of the liver and anaemia.

4.11 Withdrawal period(s)

Cattle and sheep:	Meat:	Zero days.
	Milk :	Zero hours.
Horses:	Not to be used in horses intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation.	

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Vitamins with minerals
ATCvet Code: QA11JB

5.1. Pharmacodynamic properties

Vitamin E: It is an antioxidant and is necessary for the stability and function of muscle tissues. It has a similar role to selenium and each can, to some extent, replace the other.

Selenium: The essential role of selenium is as part of the enzyme glutathione peroxidase, whose function is to prevent free-radical damage to tissue.

There is a complex interaction between the requirements of selenium and vitamin E whereby either may substitute in part for the other. A deficiency is most frequently seen in young, fast growing animals, causing degeneration of cardiac, respiratory and skeletal muscles and neurone degeneration in horses.

5.2 Pharmacokinetic particulars

Vitamin E : It is taken up by most tissues and accumulates in lipids. Following a bolus dose, approximately 70 – 80% is eliminated over a one week period.

Selenium : It is distributed via the blood to all tissues. Tissue levels start to decline after the first week but clearance from blood takes several weeks.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl hydroxybenzoate
Propyl hydroxybenzoate
Benzyl alcohol
Macrogol 15 hydroxystearate
Citric acid anhydrous
Water for Injections
Nitrogen

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of veterinary medicinal product as packaged for sale: 2 years.
Shelf life after opening of the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25ºC. Protect from light.
Following withdrawal of the first dose, used the product within 28 days.
Discard unused material.

6.5 Nature and composition of immediate packaging

100 ml amber Type II glass vials, closed with grey chlorobutyl stoppers and 20 mm aluminium crimped seals.

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
Lilly House
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RG24 9NL

8. MARKETING AUTHORISATION NUMBER

Vm 00879/4079

9. DATE OF FIRST AUTHORISATION

13 October 1994

10 DATE OF REVISION OF THE TEXT

September 2016

Approved: 30 September 2016