SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

E-SELENSOL 70/1 mg/ml emulsion for injection for cattle, sheep and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition per ml

Active substances:
All-rac-α-tocopheryl acetate (Vitamin E)..... 70 mg
Selenium (equivalent to 2.20 mg sodium selenite) ..... 1 mg

Excipients
Benzyl alcohol (E1519) ..... 20 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection
Milky, yellowish white liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, sheep, and pigs.

4.2 Indications for use, specifying the target species

Treatment and prevention of diseases caused by Vitamin E and Selenium deficiency and the associated symptomatology.

4.3 Contraindications

Do not use in animals that have consumed seleniferous grains, grasses, or forages.
Do not use in cases of hypersensitivity to the active substances or any of the excipients.

4.4 Special warnings for each target species

Given the toxicity of selenium, it is important to respect the recommended dosage. Do not administer higher doses than the recommended ones.

4.5 Special precautions for use

Special precautions for use in animals

Selenium-vitamin E deficiency syndrome produces a variety and complexity of symptoms often interfering with a proper diagnosis. Even in selenium deficient areas, there are other disease conditions which produce similar clinical signs. All these conditions should be carefully considered prior to the treatment of STD syndrome. Selenium serum levels, SGOT and CPK serum levels, and creatine/ creatinine ratio in the urine can serve as aids in arriving at a diagnosis of STD.

Do not administer by intravenous route.

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

People with known hypersensitivity to active substances should administer the veterinary medicinal product with caution.

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

In case of spillage on skin or eyes, wash immediately with plenty of water.

4.6 Adverse reactions (frequency and seriousness)

In very rare case (less than 1 animal per 10,000 treated animals, including isolated cases):

- Irritation and pain may occur at the injection site.
- Anaphylactic reactions of varying intensity may occur in previously sensitized animals.

4.7 Use during pregnancy, lactation or lay

Safety during pregnancy and lactation has not been studied. However, the use of this veterinary medicinal product in the last stage of pregnancy does not seem to provoke problems.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Intramuscular or subcutaneous administration.

Cattle

Prevention

Newborn calves: 2 ml product / animal (equivalent to 140 mg of vitamin E and 2 mg of selenium), repeat after 7 days.
Calves 1-2 weeks old: 2.5 - 3 ml product / animal (equivalent to 175 - 210 mg of vitamin E and 2.5-3 mg of selenium), repeat after 7 days.
Adults: 20 ml product / animal (equivalent to 1400 mg of vitamin E and 20 mg of selenium), 30 days before calving to prevent deficiency in calves.

Treatment
Newborn calves: 4 ml product / animal (equivalent to 280 mg of vitamin E and 4 mg of selenium),
Repeat after 7 days.
Calves 1-2 weeks old: 5 ml product / animal (equivalent to 350 mg of vitamin E and 5 mg of selenium), repeat after 7 days.

Ovine

Prevention
Newborn lambs: 0.5 ml product/ animal (equivalent to 35 mg of vitamin E and 0.5 mg of selenium), repeat after 5-7 days.
Lambs over 2 weeks old: 1 ml product/ animal (equivalent to 70 mg of vitamin E and 1 mg of selenium), repeat after 5-7 days.
Pregnant sheep: 2.5 - 4 ml product/ animal (equivalent to 175 - 280 mg of vitamin E and 2.5-4 mg of selenium), 30 days before calving to prevent deficiency in lambs.
Treatment
1 ml product/ animal (equivalent to 70 mg of vitamin E and 1 mg of selenium), repeat after 5-7 days being able to apply up to 4 times.

Porcine

Prevention
Piglets: 0.03 - 0.1 ml product/ animal (equivalent to 2.1 - 7 mg of vitamin E and 0.03 - 0.1 mg of selenium).
Adults: 1 - 3 ml product/ 25 kg b.w. (equivalent to 70 - 210 mg of vitamin E and 1-3 mg of selenium / 25 kg b.w.), repeat after 7 days.
Treatment
Piglets: 0.1 ml product/ animal (equivalent to 7 mg of vitamin E and 0.1 mg of selenium).
Adults: 2 ml product/ 25 kg b.w. (equivalent to 140 mg of vitamin E and 2 mg of selenium / 25 kg b.w.).
Breeding sows: 3-6 ml product/ 50 kg b.w. (equivalent to 210 - 420 mg of vitamin E and 3-6 mg of selenium / 50 kg b.w.), repeat after 7 days.

- Use sterilized material and strictly observe aseptic measures (clean the area, etc.)
- Shake the container well before use.
- Do not administer more than 15 ml at the same injection site.
- Use a thick needle and inject slowly.

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

Symptoms due to acute selenium toxicity can be:

In cattle and sheep, overdose is characterized by depression, ataxia, dyspnoe, tachycardia and increased risk of temperature, then there is an increase in diuresis and diarrhea. The terminal symptoms are cyanotic mucous, dilated pupils, tympany, muscle weakness, prostration and death.

In pig, anorexia, vomiting, diarrhea, lethargy, faltering gait, weakness, paresis, dyspnoe, prostration, coma and death in 1- 2 days are observed.

In case of intoxication apply a symptomatic treatment. Pulmonary oedema and circulatory shock must be combated

4.11 Withdrawal period

Meat and offal:
- Cattle: 14 days
- Pig: 14 days
- Sheep: 30 days

Not authorised for use in animals producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Selenium combinations
ATCvet code: QA12CE99

5.1 Pharmacodynamic properties

Selenium and vitamin E (all-rac-α-tocopheryl acetate) act in a complementary way protecting the cells against the accumulation of peroxides, which are the cause of cell degeneration and destruction.

Vitamin E is a fat-soluble vitamin with antioxidant activity. It avoids the oxidation of the polyunsaturated fatty acids of the membranes, thus preventing the formation of free radicals and peroxides.

Selenium is a trace element that is part of the enzyme glutathione peroxidase (GPx), responsible for the reduction of peroxides.

5.2 Pharmacokinetic particulars

Vitamin E, when administered intramuscularly, tends to be deposited at the injection site and to be released slowly. This behavior allows to detect concentrations in blood and tissues up to 20 days after administration, as well as Tmax values (time in which maximum concentrations are observed) very variable, between 7 hours and 48 hours, in sheep. After its absorption, vitamin E passes into the circulatory system joining lipoproteins and then diffuses to all tissues, stored in tissues and slowly redistributed from them, behavior that contributes to the high residence time in the body, calculated in about 47 hours in sheep As it passes through the liver, vitamin E undergoes oxidative metabolism and the resulting conjugates are excreted mainly in the bile and, to a lesser extent, in the urine and milk. The bioavailability of vitamin E is highly dependent on the formulation administered and ranges, depending on the animal species, between 40% in pigs and 51% in sheep.

Selenium, after intramuscular or subcutaneous administration, is rapidly absorbed, with maximum blood levels detected between 1 hour and 5 hours after injection, in sheep and calves. The decrease in concentrations takes place in two phases, of which the first is the fastest and during which approximately 50% of the administered dose is eliminated, with the speed of the second being slower in animals with selenium-deficient diets. This behavior

allows maintaining high levels of selenium until 20-28 days after administration, in sheep and lambs. Once in the blood, selenium is reduced to its hydrogenated form, which binds to plasma proteins. It can cross the placental barrier and is eliminated mainly by urine and feces and, in a small proportion, is excreted through milk

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Macrogol-15 hydroxystearate
Hydrochloric acid
Sodium hydroxide
Water for injections

6.2 Incompatibilities

Given the sensitivity of vitamins to oxidative substances and pH changes, this veterinary medicinal product must not be mixed with any other product.

6.3 Shelf life

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

6.4. Special precautions for storage

Keep the container in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

Type II amber coloured glass vials, with bromobutyl rubber stopper and lacquered aluminium cap.

Pack sizes:
Carton box with 1 vial of 50 ml.
Carton box with 1 vial of 100 ml

Not all pack sizes may be marketed.

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

LABIANA Life Sciences, S.A.

Venus 26
08228 Terrassa
(Barcelona) Spain

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Supply: **Veterinary medicinal product subject to prescription.**
Administration: **Administered under the control or supervision of the veterinarian.**

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGE

50 ml
100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

E-SELENSOL 70/1 mg/ml emulsion for injection for cattle, sheep and pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Composition per ml

Active substances:
All-rac-α-tocopheryl acetate (Vitamin E)..... 70 mg
Selenium (equivalent to 2.20 mg sodium selenite) ..... 1 mg

Excipients
Benzyl alcohol (E1519) ..... 20 mg
Other excipients q.s.f. ..... 1 ml

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

50 ml
100 ml

5. TARGET SPECIES

Cattle, sheep, and pigs

6. INDICATION

7. METHOD AND ROUTES OF ADMINISTRATION

Intramuscular or subcutaneous administration.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal:
- Cattle: 14 days
- Porcine: 14 days

- Sheep: 30 days

Not authorised for use in animals producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}:
Once opened use within: 28 days.

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton in order to protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

LABIANA Life Sciences, S.A.
Venus 26
08228 Terrassa (Barcelona)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
E-SELENSOL 70/1 mg/ml emulsion for injection for cattle, sheep and pigs

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 responsible for batch release:
LABIANA Life Sciences, S.A.
Venus 26
08228 Terrassa (Barcelona)
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

E-SELENSOL 70/1 mg/ml emulsion for injection for cattle, sheep and pigs

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Composition per ml

Active substances:
All-rac-α-tocopheryl acetate (Vitamin E)..... 70 mg
Selenium (equivalent to 2.20 mg sodium selenite) ..... 1 mg
Excipients
Benzyl alcohol (E1519) ..... 20 mg
Other excipients q.s.f. ..... 1 ml

4. INDICATIONS

Treatment and prevention of diseases caused by Vitamin E and Selenium deficiency and the associated symptomatology.

5. CONTRAINDICATIONS

Do not use in animals that have consumed seleniferous grains, grasses, or forages.
Do not use in cases of hypersensitivity to the active substances or any of the excipients.

6. ADVERSE REACTIONS

In very rare case (less than 1 animal per 10,000 treated animals, including isolated cases):
- Irritation and pain may occur at the injection site.
- Anaphylactic reactions of varying intensity may occur in previously sensitized animals.

The frequency of adverse reactions should be classified according to the following groups:
- Very frequently (more than 1 animal for every 10 treated animals presents adverse reactions)
- Frequently (more than 1 but less than 10 animals per 100 treated animals)
- Infrequently (more than 1 but less than 10 animals per 1,000 treated animals)
- On rare occasions (more than 1 but less than 10 animals per 10,000 treated animals)

- Very rarely (less than 1 animal per 10,000 treated animals, including isolated cases

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, sheep, and pigs.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Intramuscular or subcutaneous administration.

Dosage

Cattle

Prevention

Newborn calves: 2 ml product / animal (equivalent to 140 mg of vitamin E and 2 mg of selenium), repeat after 7 days.
Calves 1-2 weeks old: 2.5 - 3 ml product / animal (equivalent to 175 - 210 mg of vitamin E and 2.5-3 mg of selenium), repeat after 7 days.
Adults: 20 ml product / animal (equivalent to 1400 mg of vitamin E and 20 mg of selenium), 30 days before calving to prevent deficiency in calves.

Treatment
Newborn calves: 4 ml product / animal (equivalent to 280 mg of vitamin E and 4 mg of selenium),
Repeat after 7 days.
Calves 1-2 weeks old: 5 ml product / animal (equivalent to 350 mg of vitamin E and 5 mg of selenium), repeat after 7 days.

Ovine

Prevention
Newborn lambs: 0.5 ml product/ animal (equivalent to 35 mg of vitamin E and 0.5 mg of selenium), repeat after 5-7 days.
Lambs over 2 weeks old: 1 ml product/ animal (equivalent to 70 mg of vitamin E and 1 mg of selenium), repeat after 5-7 days.
Pregnant sheep: 2.5 - 4 ml product/ animal (equivalent to 175 - 280 mg of vitamin E and 2.5-4 mg of selenium), 30 days before calving to prevent deficiency in lambs.
Treatment
1 ml product/ animal (equivalent to 70 mg of vitamin E and 1 mg of selenium), repeat after 5-7 days being able to apply up to 4 times.

Porcine

Prevention
Piglets: 0.03 - 0.1 ml product/ animal (equivalent to 2.1 - 7 mg of vitamin E and 0.03 - 0.1 mg of selenium).
Adults: 1 - 3 ml product/ 25 kg b.w. (equivalent to 70 - 210 mg of vitamin E and 1-3 mg of selenium / 25 kg b.w.), repeat after 7 days.

Treatment
Piglets: 0.1 ml product/ animal (equivalent to 7 mg of vitamin E and 0.1 mg of selenium).
Adults: 2 ml product/ 25 kg b.w. (equivalent to 140 mg of vitamin E and 2 mg of selenium / 25 kg b.w.).
Breeding sows: 3-6 ml product/ 50 kg b.w. (equivalent to 210 - 420 mg of vitamin E and 3-6 mg of selenium / 50 kg b.w.), repeat after 7 days.

9. ADVICE ON CORRECT ADMINISTRATION

- Use sterilized material and strictly observe aseptic measures (clean the area, etc.)
- Shake the container well before use.
- Do not administer more than 15 ml at the same injection site.
- Use a thick needle and inject slowly.
- Use a thick needle and inject slowly.

10. WITHDRAWAL PERIOD

Meat and offal:
- Cattle: 14 days
- Pig: 14 days
- Sheep: 30 days

Not authorised for use in animals producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the container in the outer carton in order to protect from light.
Once opened the immediate package, use within 28 days.
Do not use this veterinary medicinal product after the expiry date which is stated on the label or carton after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Special warnings for each target species:

Given the toxicity of selenium, it is important to respect the recommended dosage. Do not administer higher doses than the recommended ones.

Special precautions for use in animals:

Selenium-vitamin E deficiency syndrome produces a variety and complexity of symptoms often interfering with a proper diagnosis. Even in selenium deficient areas, there are other disease conditions which produce similar clinical signs. All these conditions should be carefully considered prior to the treatment of STD syndrome. Selenium serum levels, SGOT and CPK serum levels, and creatine/ creatinine ratio in the urine can serve as aids in arriving at a diagnosis of STD.

Do not administer by intravenous route.

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

People with known hypersensitivity to active substances should administer the veterinary medicinal product with caution.

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

In case of spillage on skin or eyes, wash immediately with plenty of water.

Pregnancy and lactation:

Safety during pregnancy and lactation has not been studied. However, the use of this veterinary medicinal product in the last stage of pregnancy does not seem to provoke problems.

Interaction with other medicinal products and other forms of interaction:

None known.

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

Symptoms due to acute selenium toxicity can be:

In cattle and sheep, overdose is characterized by depression, ataxia, dyspnoe, tachycardia and increased risk of temperature, then there is an increase in diuresis and diarrhea. The terminal symptoms are cyanotic mucous, dilated pupils, tympany, muscle weakness, prostration and death.

In pig, anorexia, vomiting, diarrhea, lethargy, faltering gait, weakness, paresis, dyspnoe, prostration, coma and death in 1- 2 days are observed.

In case of intoxication apply a symptomatic treatment. Pulmonary oedema and circulatory shock must be combated

Incompatibilities:

Given the sensitivity of vitamins to oxidative substances and pH changes, this veterinary medicinal product must not be mixed with any other product.

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED