VIM SEL INJECTION

(Alpha Tocopheryl Acetate (Vit E), Sodium Selenite)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

VIM SEL INJECTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml Contains:
Alpha Tocopheryl Acetate (Vit E) ... 50mg
Sodium Selenite …… 0.50mg

3. PHARMACEUTICAL FORM

Emulsion for Injection

4. CLINICAL INFORMATION

4.1. Target species

Cattle, Sheep & Goat,.

4.2. Indications for use specifying the target species

In all species, treatment and prevention of vitamin E and selenium deficiency states.

4.3. Contraindications

Do not use in animals that ingest grasses, forages or concentrates with high selenium content.
Do not use in cases of known hypersensitivity to the active ingredient and/or any of the excipients

4.4. Special warnings for each target species

Due to selenium's toxicity, it is important to adhere to the dosage guidelines. Do not administer doses higher than those recommended.

4.5. Special precautions for use

This medicine does not contain any antimicrobial preservatives.

Special precautions for safe use in the target species:

Selenium-vitamin E deficiency syndrome produces a variety and complexity of symptoms that often interfere with proper diagnosis. Even in selenium-deficient areas, other diseases present similar clinical signs, which is why symptoms should be carefully evaluated before applying treatment. Serum selenium, SGOT, and CPK levels, and the urine creatine/creatinine ratio, can be helpful in diagnosing the disease.
Do not administer intravenously.

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

People with known hypersensitivity to the active substances should avoid contact with the veterinary medicinal product.
Avoid contact with eyes, skin, and mucous membranes.
Wash hands thoroughly after handling the product.
Keep out of reach of children.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label.

4.6. Adverse reactions (frequency and seriousness)

Bovino, ovino, caprino,

Very rare Very rare (<1 animal per 10,000 animals treated, including isolated reports):	Irritation at the injection site Pain at the injection site Anaphylaxis*

*Of varying intensity in previously sensitized animals
Reporting adverse events is important. It allows for continued monitoring of the safety of a veterinary medicinal product. Reports should preferably be sent via a veterinarian to the Marketing Authorisation Holder or their local representative, or to the national competent authority via the national reporting system. Please also refer to the respective contact details in section 16 of the package leaflet.

4.7. Use during pregnancy and lactation or lay

The safety of this veterinary medicinal product has not been demonstrated during pregnancy or lactation.
Gestation: The use of the veterinary medicine in the last stages of pregnancy does not appear to pose any problems

4.8. Interaction with other veterinary medicinal products and other forms of interaction

None known.

4.9. Dosage and administration route

Intramuscular or subcutaneous route

Bovine: 1-1.5 ml of medication/15 kg bw (equivalent to 50-75 mg of vitamin E and 0.5-0.75 mg of selenium/15 kg bw), repeat every 2-4 weeks if necessary.

Sheep and goats: Lambs and kids older than 2 weeks: 1 ml of medication/15 kg body weight (equivalent to 50 mg of vitamin E and 0.5 mg of selenium/15 kg body weight).
Sheep and goats: 1.5 ml of medication/15 kg bw (equivalent to 75 mg of vitamin E and 0.75 mg of selenium/15 kg bw), after the third month of gestation to prevent deficiency in lambs and kids.

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

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

Symptoms due to acute selenium toxicity may include:
In ruminants, overdose is characterized by depression, ataxia, dyspnea, tachycardia, and fever, followed by increased urine output and diarrhea. Terminal symptoms include cyanotic mucous membranes, dilated pupils, tympany, muscle weakness, prostration, and death.
In cases of poisoning, apply symptomatic treatment. Pulmonary edema and circulatory shock should be treated.

4.11. Special restrictions on use and special conditions of use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products, in order to limit the risk of development of resistance

Administration under the control or supervision of the veterinarian

4.12. Withdrawal period:

Meat
Bovine: 14 days
Sheep: 30 days
Goat: 30 days

Milk Its use is not authorized in animals whose milk is used for human consumption.

5. PHARMACOLOGICAL PROPERTIES

ATCvet code: **QA12CE99**

5.1. Pharmacodynamics properties

Selenium and vitamin E (all-rac-ÿ-tocopheryl acetate) act in a complementary manner, protecting cells from the accumulation of peroxides, which are the cause of cell degeneration and destruction.
Vitamin E is a fat-soluble vitamin with antioxidant activity. It prevents the oxidation of polyunsaturated fatty acids in 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 information

Vitamin E, when administered intramuscularly, tends to be deposited at the injection site and released slowly. This behavior allows concentrations to be detected in blood and tissues up to 20 days after administration, as well as highly variable tmax values (time at which maximum plasma concentrations are observed), between 7 hours and 48 hours, in sheep. After absorption, vitamin E reaches the circulatory system by binding to lipoproteins and subsequently diffuses to all tissues, being stored in tissues and slowly redistributed from them, a behavior that contributes to the long average residence time in the body, estimated at approximately 47 hours in sheep. Upon passing through the liver, vitamin E undergoes oxidative metabolism, and the resulting conjugates are excreted mainly in the bile and, to a lesser extent, in urine and milk. The bioavailability of vitamin E is highly dependent on the formulation administered and ranges, depending on the animal species, 51% in sheep.

Selenium, after intramuscular or subcutaneous administration, is rapidly absorbed, with peak blood levels detected between 1 and 5 hours after injection in sheep and calves. The decline in concentrations occurs in two phases, the first of which is the most rapid and during which approximately 50% of the administered dose is eliminated.

The rate of selenium excretion is the second slowest in animals on selenium-deficient diets. This behavior allows high selenium levels to be maintained for up to 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 primarily in urine and feces, and, to a small extent, is excreted in milk.

6. PHARMACEUTICAL INFORMATION

6.1. List of excipients

Macrogolglycerol ricinoleate
Polysorbate 80
Propylene glycol
Water for injections

6.2. Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the container: use within 28 days, do not store.

6.4. Special precautions for storage

Store below 25°C.
Protect from light and moisture.
Keep out of the reach of children.
To be used as directed by the registered veterinary practitioner only.

6.5. Nature and composition of primary conditioning

Cardboard box with glass injection vial (s).
Vial is closed with a bromobutyl rubber stopper and sealed with an aluminum flip off seal.
Pack sizes: 100ml

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF WASTE MATERIALS
UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS

Waste materials derived from the use of such products
Medicinal products should not be disposed of via wastewater or household waste.
Use return systems for unused veterinary medicinal products or waste materials derived from such products, in accordance with local requirements and national collection systems applicable to the veterinary medicinal product concerned.
Treated animals should be kept in shelters throughout the treatment period and their droppings should be collected and NOT used for soil fertilization.

7. MARKETING AUTHORISATION HOLDER

Nawan Laboratories (Pvt.) Ltd.
Plots No. 136-138, Sector-15,
Korangi Industrial Area, Karachi-74900, Pakistan.

8. MARKETING AUTHORISATION NUMBER

Reg. No.: 053998

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 31-03-2009

10. DATE OF REVISION OF THE TEXT

17-02-2025