VIM-SEL ORAL SOLUTION

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

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

VIM-SEL Oral Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml Contains:
Alpha Tocopheryl Acetate (Vit E) …..100mg
Sodium Selenite..... 2 mg

3. PHARMACEUTICAL FORM

Oral Solution

4. CLINICAL INFORMATION

4.1. Target species

Poultry

4.2. Indications for use specifying the target species

Prevention and treatment of selenium and vitamin E deficiency states such as: Exudative diathesis, Encephalomalacia.
Encephalomalacia and exudative diathesis in chickens; muscular dystrophy in newborn animals; rickets and osteomalacia; to promote spermatogenesis in male animals, fertilization and gestation in female animals; to improve egg-laying in laying hens; to enhance resistance to diseases in young animals and birds.

4.3. Contraindications

Should not be used in case of hypersensitivity to the active substances or to any of the excipients

4.4. Special warnings for each target species

Not Applicable

4.5. Special precautions for use

Special precautions for use in animals:

None

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)

Unknown.
The frequency of adverse reactions is determined by the following classification:
Very common (more than 1 in 10 treated animals exhibiting adverse reactions)
Frequent (more than 1 but less than 10 animals per 100 treated animals)
Infrequent (more than 1 but less than 10 animals per 1,000 treated animals)
Rare (more than 1 but less than 10 animals per 10,000 treated animals)
Very rare (less than 1 animal per 10,000 treated animals, including isolated cases) messages).

4.7. Use during pregnancy and lactation or lay

In the absence of specific studies in the target species, use only in accordance with the benefit/risk assessment by the responsible veterinarian.

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

An antagonism has been established between iron and selenium compounds. The simultaneous administration of copper and selenium does not positively affect the growth of animals.

4.9. Dosage and administration route

Oral route.

0.022 mg selenium and 9.1 mg vitamin E per kg body weight for 5 consecutive days orally in drinking water approximately 1 ml solution per litre of drinking water for 5 days, then 0.022 mg selenium and 9.1 mg vitamin E per kg body weight 2 days per week during the risk period if necessary.

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

In case of overdose, selenium leads to toxic manifestations.

4.11. Withdrawal Period:

Meat and internal organs: zero days.
Milk: zero days.
Eggs: zero days.

5. HARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Selenium, combinations
ATCvet code: **QA12CE99**

5.1. Pharmacodynamic properties

Combines the action on the metabolism of selenium, , and vitamin E. Sodium selenite enhances the action of vitamin E. It participates in the processes of tissue respi- ration and oxidative phosphorylation. As an antioxidant, it prevents the formation of per- oxides from unsaturated fatty acids, which are involved in the pathogenesis of encepha- lomalacia in chickens, muscular dystrophy, and other myopathies in animals. It stimulates fertility and growth. Tocopherol (vitamin E) exhibits antioxidant activity and protects hor- mones, enzymes, lipids, and other vitamins from oxidative destruction. It helps stabilize and absorb vitamin A and carotene; it participates in the metabolism of proteins, fats, and carbohydrates. It prevents the formation of abnormal phospholipids and favors the func- tion of striated muscle, including the cardiac muscle. It strengthens capillaries, promotes spermatogenesis and fertilization ability, and improves the carrying of the fetus; it stimu- lates egg-laying and the hatchability of eggs in birds.Cholecalciferol (vitamin D3) ensures the absorption of calcium and phosphorus compounds in the intestines, regulates their optimal levels in the body, and improves the metabolism of substances in the skin, the function of the digestive system, and the liver.

5.2. Pharmacokinetic information

The principal mechanism of action associated with the physiological and pharmacological effect of selenium is expressed in its antioxidant effect in the cell membrane against hy- drogen peroxide and lipoperoxides. This effect is related to that of glutathione peroxidase, which contains selenocysteine. The protective antioxidant action of selenium is primarily associated with that of vitamin E. Selenocysteine is also included as a component in other functional proteins such as tetra-iodothyronine-5-I-deiodinase (including in the metabo- lism of thyroid hormone), but the complete biochemical model of selenium's action in the body is still being clarified. Selenium is necessary for the enzyme glutathione peroxidase, which facilitates the reduction of hydrogen peroxide. There is an overlap in the action of selenium and vitamin E regarding their responsibility for reducing peroxides in tissues. Vitamin D is the generic name for steroids with anti-rickets activity. Vitamin D is ab- sorbed and retained in all tissues of the body. High levels have been found in the liver and in fat tissues. When functional activity is needed, vitamin D is converted into its 25-hy- droxy derivative (25-OHD) in the liver. Under the influence of parathyroid hormone, 25-OHD is converted into the final functional form 1,25-dihydroxycholecalciferol or 1,25-(OH)2D3 in the kidneys.

The rate of formation of 1,25-(OH)2D3 is regulated by a specific renal hydroxylase. The increase in the activity of this enzyme is directly modulated by a low concentration of (Ca++) ions and indirectly by a low (PO4) ion,

which causes the release of parathyroid hormone. It is also triggered by a low circulating level of phosphate (PO4) ions. The functions of vitamin D consist of the following: It maintains the circulat- ing levels of calcium ions (Ca++) in the blood, which is important for many other func- tions of the body. Vitamin D and parathyroid hormone together mobilize (Ca++) and (PO4) from the bones, i.e., vitamin D is clinically used to aid bone strength and growth. It is certain that calcium (Ca++) and phosphate (PO4) ions are present in the blood in a highly saturated concentration, such that bones can be formed. The second very important function of vitamin D is the activation of the transport system of intestinal epithelial cells, which increases the absorption of (Ca++) and (PO4)-ions. This obviously depends on a significant daily intake of appropriate (Ca++) and (PO4)-ions. Additionally, vitamin D activates renal tubular cells, which are involved in the reabsorption of (PO4) and possibly also of (Ca++)-ions. Vitamin E is the name given to a group of biologically active tocoph- erols. There is a long-standing debate regarding the biological role of vitamin E, as its role in the reproduction of rats was initially established. However, this is not necessarily the case for other animal species. Its most important role is that of an antioxidant, i.e., to prolong the life of polyunsaturated fatty acids by protecting them from oxidation. This function is expressed in stabilizing cell membranes, as polyunsaturated fatty acids are an important building block of cell membranes. More importantly, vitamin E prevents or even slows down the formation of free radicals and the hyperoxidation of polyunsaturated fatty acids.

Pharmacological levels of vitamin E also provide grounds to accept that it enhances the

immune system and increases the resistance of organisms to infectious diseases.

6. PHARMACEUTICAL INFORMATION

6.1 List of excipients

Potassium sorbate
Methyl parahydroxybenzoate
Citric acid monohydrate
Disodium phosphate dodecahydrate
Polyoxyethylene castor oil
Diluted hydrochloric acid
Purified water

6.2 Incompatibilities

An antagonism has been established between iron and selenium compounds. The simultaneous administration of copper and selenium does not positively affect the growth of animals.

6.3. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

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

Plastic bottles with plastic cap tightly sealed by induction seal.
Pack size: 100ml & 1 Liter

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

Any unused veterinary medicinal products or waste materials derived from such medicinal products should be disposed of in accordance with local requirements and placed in appropriate collection and disposal systems for unused or expired medicinal products.

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.: 053999

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 31-03-2009

10. DATE OF REVISION OF THE TEXT

31-01-2025