SE-BE 12 INJECTION

(Sodium Selenite, Vitamin E, Vitamin B12, Vitamin B1, Adenosine 5-Monophosphate)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

SE-BE 12 INJECTION.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Sodium Selenite……..……..…….0.5mg
Vitamin E Acetate……..…..…70mg
Vitamin B12……..…..…….0.1mg
Vitamin B1……..20mg
Adenosine 5-Monophosphate……5mg

3. PHARMACEUTICAL FORM

Solution for Injection.

4. CLINICAL INFORMATION

4.1. Target species

Cattle, Sheep, Lamb, poultry & Horse.

4.2. Indications for use specifying the target species

SE-BE 12 Injection is indicated in therapy and prophylaxis of muscular dystrophy in calves, lambs, muscle overload; neuritis, myositis, myasthenia; hepatosis dietetica and microangiopathy.

4.3. Contraindications

Do not administer to animals with known hypersensitivity to components of the preparation

4.4. Special warnings for each target species

None.

4.5. Special precautions for use

Special precautions for safe use in the target species:

Apply normal aseptic precautions.

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

People with known hypersensitivity to the active substances must avoid contact with the veterinary medicinal product. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the doctor. Avoid contact with eyes and skin, in case of contact wash with plenty of water.

4.6. Adverse reactions (frequency and seriousness)

Rarely allergic reactions can occur

4.7. Use during pregnancy and lactation or lay

It can be used during pregnancy and lactation

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

Sulphurated compounds and copper salts reduce the toxicity of selenium. Absorption and accumulation of vitamin A are intensified by vitamin E

4.9. Dosage and administration route

The dosage can be administered by the intramuscular, subcutaneous or intravenous routes (very slow in the latter case) at the following doses:

Calves: 10 - 20 ml
Lambs: 10 ml
Horses: 10 - 20 ml
Poultry: 0.1ml per kg body weight by subcutaneous, intramuscular route or, alternatively, 1ml in 5-6 liters of drinking water.

As a therapeutic agent: administer the indicated dose once a day for 5 days.
As prophylaxis in myodystrophy: administer the indicated dose once a week, for 5 weeks, starting from the 10th day of life.

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

Symptoms of overdosage of selenium are depression, ataxia, dyspnea, diarrhoea, muscular weakness.

4.11. Restrictions and special conditions of use, including restrictions on the use of antimicrobial and antiparasitic veterinary drugs, in order to reduce the risk of resistance development

Medication administered under the control or supervision of the veterinarian

4.12. Withdrawal period:

Meat and offal: 0 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: combinations of vitamins and minerals
ATC Vet Code: **QA11AA03**

5.1. Pharmacodynamics properties

SE-BE 12 is a solution for injection based on different active substances, which, preventing the formation of peroxides, prevent the consequent degeneration of the various tissues. Selenium is a indispensable element for the activity of glutathione-peroxidase, an enzyme which plays a very important role in protection of tissues from damage by the peroxides which form in the course of metabolic processes. Vitamin E acts as an antioxidant on cell membranes, thus integrating the protective action of selenium. Vitamin B12 stimulates the cellular turnover and growth, intervening in the synthesis of nucleic acids and proteins. Adenosin-5'-monophosphoric acid (AMP) is an adenylic derivative which intervenes in synthesis of nucleic acids and of ATP. Adenosin-5'-monophosphoric acid intervenes in carbohydrate metabolism, regulating the phosphorylation of sugars; therefore, the energy for muscle contraction, as well as nutrition of the myocardium, depends on this. SE-BE 12 is therefore indicated in therapy and prevention of degenerative disorders to the muscular, neuromuscular, cardiac, hepatic, pancreatic and reproductive systems. SE-BE 12 also favours physical recovery of treated animals, which do not undergo delayed or arrested development.
Thiamine functions as a crucial cofactor for several enzymes involved in carbohydrate metabolism, particularly in the decarboxylation of alpha-ketoacids, thereby playing a vital role in energy production and nerve impulse transmission in animals.

5.2. Pharmacokinetic information

Administered by the subcutaneous or intramuscular routes, selenium is rapidly absorbed, becoming localised in the erythrocytes, with ample distribution to the various tissues. This rapid absorption is also followed by rapid excretion, by both the urinary and fecal routes. Vitamin E is transported in the circulation by beta-lipoproteins. It distributes plentifully to all tissues and is stored in the liver, where it is partly metabolised. The principal excretory route is the bile, while very small part is excreted with the urine. Vitamin B12 binds to specific proteins and distributes rapidly to all tissues, particularly the liver, where it is stored. Any excess is excreted principally by the renal route. Adenosin-5'-monophosphoric acid (AMP) is rapidly metabolised in the tissues for synthesis of nucleic acids and ATP.
Thiamine is rapidly absorbed from the gastrointestinal tract, distributed widely with higher concentrations intracellularly, and any excess not utilized is primarily excreted in the urine as metabolites.

6. PHARMACEUTICAL INFORMATION

6.1 Incompatibilities

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

6.2. Shelf life

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

6.3. Special precautions for storage

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

6.4. Nature and composition of primary conditioning

100 ml Type I or Type II glass bottles, with an elastomer closure and aluminium collar in a cardboard box.

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.: 125747

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 19-03-2025

10. DATE OF REVISION OF THE TEXT

19-03-2025