ADE-VET INJECTION
(Vitamin A, D3 & E)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

ADE-VET Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml Contains:
Vitamin A …….. 80, 000 IU
Vitamin D3 ……. 40,000 IU
Vitamin E ……. 20 mg

3. PHARMACEUTICAL FORM

Solution for Injection.

4. CLINICAL INFORMATION

4.1. Target species

Cattle, Horses, Sheep, Goat

4.2. Indications for use specifying the target species

Vitamin ADE is required in case of stress, improper feeding, disease estates and their convalescence, growing and laying period. A supplement of vitamin deficiencies, stress conditions, production performances. Promote anti-body and convalescing birds.
To prevent stress & vitamin A, D3, E, deficiency. To improve health conditions of birds.
To improve productivity, growth rate, egg production hatchability. To improve egg shell quality.
Effective in coccidiosis. Effective in debeaking.

For use in Cattle, Horses, Sheep, Goat & Poultry to prevent and treat deficiencies in vitamins A, D, E, associated with:

- Nutritional deficiencies: Inadequate intake of vitamins in the diet.
- Malabsorption: Conditions that impair the absorption of vitamins from the gut.
- Liver disease: Impaired vitamin storage and metabolism.
- Stress: Increased vitamin requirements during stress periods.
- Growth and development: Increased vitamin needs during periods of rapid growth.
- Reproductive problems**:** Deficiencies can affect fertility, pregnancy, and lactation.

4.3. Contraindications

Do not administer to animals with known hypersensitivity to any of the vitamins A, D,E.
Use with caution in animals with pre-existing liver or kidney dysfunction, as excessive vitamin intake may exacerbate these conditions.
Monitor animals closely for any signs of hypervitaminosis A, D, or E, such as anorexia, lethargy, vomiting, and diarrhea

4.4. Special warnings for each target species

Cattle:

Milk Withdrawal Time: Observe appropriate milk withdrawal times as per local regulations to avoid potential residues in milk.
Pregnancy and Lactation: Use with caution in pregnant and lactating cows. Monitor for any potential effects on the dam or offspring.
Liver Disease: Exercise caution in animals with pre-existing liver disease, as the liver plays a crucial role in vitamin metabolism and storage.

Horses:

Performance Horses: Be mindful of potential drug interactions and the impact of vitamin supplementation on performance testing.
Pregnancy and Lactation: Use with caution in pregnant and lactating mares. Monitor for any potential effects on the foal.

Sheep & Goat:

Pregnancy and Lactation: Use with caution in pregnant and lactating ewes. Monitor for any potential effects on the lamb.
Wool Production: Be aware that excessive vitamin A intake can potentially impact wool quality.

Poultry deficiencies also reduce egg production and hatchability.

4.5. Special precautions for use

Special precautions for use in animals

Use with caution in animals with pre-existing liver or kidney dysfunction. Monitor animals for signs of vitamin toxicity (hypervitaminosis A, D, or E). Avoid excessive supplementation, as hypervitaminosis can occur.
Consider individual animal needs and nutritional status before administration. 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)

While generally well-tolerated, excessive supplementation with vitamins A, D, E, can lead to the following adverse reactions:
Vitamin A:
Hypervitaminosis A: Anorexia, lethargy, vomiting, diarrhea, bone pain, liver damage, central nervous system disturbances, and teratogenic effects (in pregnant animals).

Vitamin D:
Hypervitaminosis D: Anorexia, vomiting, polyuria, polydipsia, muscle weakness, cardiac arrhythmias, calcification of soft tissues, and renal failure.
Vitamin E:
Less common: Potential for gastrointestinal upset, muscle weakness, and in some cases, neurological signs.

4.7. Use during pregnancy and lactation or lay

Can be used during Pregnancy.

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

No Data Available.

4.9. Dosage and administration route

Generally 1ml/30kg body weight.

For intramuscular or subcutaneous administration

Dosage:

Cattle & Horses: 10-20ml per 200 -300kg body weight.
Calves: 5ml per 150kg body weight.
Sheep & Goat: 1ml per 30kg body weight.

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

Of the fat-soluble vitamins (A, D & E), A and D in particular can be toxic in overdose. Different animal species have different sensitivities to the (side) effects of vitamins A and D. In case of overdose of vitamin A, both acute and chronic intoxication symptoms occur. Acute symptoms are listlessness, anorexia, muscle weakness, vomiting and diarrhea; the most important chronic effect is the development of bone abnormalities. The most important intoxication symptom that occurs in case of overdose of vitamin D is hypercalcemia, in which calcium is withdrawn from the body and the calcium balance in the body is disturbed. Consequences of this include bone decalcification, effects on the cardiovascular system, kidney stones and calcium deposits in the soft tissues.

4.11. Withdrawal Period:

Zero Day.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Vitamins, (Multivitamins)
ATCvet code: **QA11BA**

5.1. Pharmacodynamic properties

Vitamin A is necessary for at least five different physiological processes:

- normal vision
- maintenance of epithelial integrity
- normal reproductive function and embryonic development
- bone development
- immunity

Consequently, deficiencies in these can lead to a wide variety of disorders related to the processes mentioned above:

In cattle, deficiency can lead to reduced feed intake, retarded growth, nyctalopia, xerophthalmia, lacrimation, diarrhea, reproductive abnormalities, and increased susceptibility to infections.

In sheep, similar symptoms occur, as well as changes in wool structure and wool strength.

Poultry deficiencies also reduce egg production and hatchability.

Horses develop eye lesions and visual abnormalities similar to those seen in ruminants, reproductive disorders, anorexia and progressive weakness.

Vitamin D is mainly involved in the regulation of parathyroid hormone secretion and the regulation of calcium and phosphorus metabolism, necessary for normal intestinal absorption, renal excretion and bone mineralization of these elements. The main signs of vitamin D deficiencies are associated with skeletal abnormalities, associated with rickets.

Vitamin E is mainly effective for its antioxidant properties, which are necessary for the proper functioning of a number of physiological structures and processes, including membrane structures (stability and integrity), prostaglandin biosynthesis, blood coagulation, reproductive function and immunity.

5.2. Pharmacokinetic information

Vitamin A is absorbed from the intestine after hydrolysis by retinyl ester hydrolase, secreted by the pancreas. Fatty micelles present in the intestine facilitate the uptake of retinol by enterocytes. Retinol is then esterified, mainly with palmitate and taken up by chylomicrons, to be transported via the lymphatic system to the liver. The liver contains about 90% of the total vitamin A content in the body.
Vitamin A is excreted mainly through urine and feces.

Vitamin D is absorbed together with existing fats and is consequently stimulated by bile and pancreatic secretions. Absorbed vitamin D is taken up by chylomi- crons together with other fats for transport via the lymphatic system to the blood- stream. Vitamin D3 (cholecalciferol) is converted to 25 hydroxycholecalciferol (calcifediol) in the liver and subsequently to the active metabolite 1, 25- dihydroxycholecalciferol (calcitriol) in the kidneys. Excretion of absorbed vitamin D and its metabolites occurs mainly via the feces with the help of bile salts. Only very little vitamin D appears in the urine.

The absorption of vitamin E is dependent on fat digestion and is therefore also facilitated by bile and pancreatic secretions. Vitamin E esters, present in the diet, are hydrolyzed in the intestinal mucosa. Most vitamin E is therefore absorbed as the free alcohol to be transported via the lymph and further via the bloodstream. Vitamin E is stored in all tissues, but mainly in the liver. Vitamin E is metabolized in the liver and excreted mainly via the bile (70-80%) and urine.

6. PHARMACEUTICAL INFORMATION

6.1 Incompatibilities

Vitamins A, D3 and E, are incompatible with oxidizing substances, strong acids and alkalis.

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, do not store.

6.3. Special precautions for storage

Store below 30°C.
Protect from light.
Do not store in the refrigerator or freezer.
Keep out of reach of children.

6.4. Nature and composition of primary conditioning

Amber color glass vial of 100ml with bromobutyl rubber stopper and aluminium flip off seal.

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.: 125639

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 26-12-2024

10. DATE OF REVISION OF THE TEXT

14-02-2025

MANUFACTURED BY:

NAWAN LABORATORIES (PVT) LTD.
136, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan.