

ADEK EXCEL ORAL SOLUTION

(Vitamin A, D3, E, K3)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

ADEK EXCEL ORAL SOLUTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml Contains:

Vitamin A.....10, 000 IU
Vitamin D3.....2,000 IU
Vitamin E..... 4 mg
Vitamin K3.....2 mg

3. PHARMACEUTICAL FORM

Oral Solution.

4. CLINICAL INFORMATION

4.1. Target species

Cattle, Horses, Sheep & Poultry

4.2. Indications for use specifying the target species

Vitamin ADEK is required in case of stress, improper feeding, disease states 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, K 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 de-beaking.

For use in Cattle, Horses, Sheep & Poultry to prevent and treat deficiencies in vitamins A, D, E, and K 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, or K. 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:

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.

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, or K 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.

Vitamin K:

Hemorrhage: In rare cases, excessive vitamin K intake can lead to bleeding tendencies due to potential interference with anticoagulant therapy.

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

Vitamin ADEK may interact with certain medications. Anticoagulants, such as warfarin, may have their effectiveness reduced when administered concurrently with Vitamin ADEK due to Vitamin K's role in blood clotting. Medications that impair liver function, including some antibiotics and anti-parasitic, can interfere with the metabolism and storage of vitamins in the liver. Additionally, substances like mineral oil and cholestyramine can hinder the absorption of fat-soluble vitamins, including those in Vitamin ADEK. Finally, concurrent administration of other vitamin or mineral supplements could lead to excessive intake and potential toxicity.

4.9. Dosage and administration route

1ml per 10 liters of drinking water should be used within 24 hours.

Poultry: 1ml per 2-3 liter drinking water for 3 - 5 days.

Calves, goats and sheep: 1 ml per 10 kg body weight for 3 - 5 days.

Cattle & Horse: 1 ml per 20 kg body weight for 3 - 5 days.

- By Oral Route Only

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

Data not available. Do not exceed recommended doses

4.11. Withdrawal period:

Meat: 28 days

Milk: 0 day.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Vitamins, Combination of Vitamins

ATCvet code: **QA11BA**

5.1. Pharmacodynamics 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, exophthalmia, 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.

Vitamin K, a fat-soluble vitamin, plays a crucial role in blood clotting.

It functions as a cofactor for an enzyme complex that carboxylates specific glutamate residues within precursor proteins of coagulation factors II (prothrombin), VII, IX, and X. This carboxylation step is essential for activating these factors, which subsequently participate in the blood clotting cascade, culminating in the formation of a stable blood clot. Consequently, vitamin K deficiency can lead to impaired blood clotting. Oral administration of vitamin K can effectively correct this deficiency by restoring normal blood clotting function. Furthermore, regular vitamin K supplementation can prevent deficiencies, particularly in animals with limited access to vitamin K-rich foods or those receiving medications that interfere with vitamin K metabolism. Vitamin K absorption is facilitated by bile acids in the gastrointestinal tract, while its metabolism primarily occurs in the liver. Excretion of vitamin K occurs predominantly through bile and urine

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 chylomicrons together with other fats for transport via the lymphatic system to the bloodstream. 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.

Vitamin K, a fat-soluble vitamin, is absorbed from the gastrointestinal tract with the aid of bile acids and dietary fats. Once absorbed, it binds to carrier proteins and is primarily distributed to the liver for metabolism and storage. In the liver, vitamin K is metabolized into active forms like menaquinone-4 and menaquinone-7. Excretion primarily occurs through bile and urine. Factors influencing pharmacokinetics include dietary fat intake, bile acid secretion, antibiotic use, and interactions with other medications. The appropriate dosage and monitoring of blood coagulation parameters are essential for effective vitamin K therapy in veterinary medicine

6. PHARMACEUTICAL INFORMATION

6.1. 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.

6.2. Special precautions for storage

Store at below 30°C.
Protect from Heat & light.
Keep out of the reach of children.
To be used as directed by the registered veterinary practitioner only.

6.3. Nature and composition of primary conditioning

Plastic bottles with 1L.

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.: 058985

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 28-08-2009

10. DATE OF REVISION OF THE TEXT

05-10-2024