

ADE-MAX ORAL SOLUTION

(Vitamin A, Vitamin D3 & Vitamin E)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

ADE-MAX ORAL SOLUTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml Contains:

Vitamin A 100,000 IU
Vitamin D3 40,000 IU
Vitamin E 40mg

3. PHARMACEUTICAL FORM

Oral Solution.

4. CLINICAL INFORMATION

4.1. Target species

Cattle, Horse, Sheep, Goat and Poultry.

4.2. Indications for use specifying the target species

For the treatment of hypo- and avitaminoses A, D3 and E in cattle, horses, sheep, goats and poultry.

4.3. Contraindications

Do not use in case of bone deformities and hypercalcemia.

4.4. Special warnings for each target species

None.

4.5. Special precautions for use

Special precautions for safe use in the target species:

To avoid overdose, the recommended dosage should be respected.

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

Avoid direct contact with skin. Wash hands thoroughly after use. Personal protective equipment, including waterproof gloves, must be worn when handling the veterinary medicinal product.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or label to the doctor.

Special precautions for environmental protection

Not applicable.

4.6. Adverse reactions (frequency and seriousness)

No side effects are expected with normal use.

4.7. Use during pregnancy and lactation or lay

Product is not recommended during pregnancy and lactation.

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

Vitamin E and other antioxidants biologically inhibit the breakdown of vitamin A and vitamin D.

- Bile salts and pancreatic enzymes, necessary for the digestion of fats, promote the absorption of fat-soluble vitamins.

However, too much dietary fat negatively affects vitamin absorption.

4.9. Dosage and administration route

Solution for oral use.

The following dosages can be used as a guideline:

Animal species	dosage
Horse	15-20 ml
Foal	0.3-0.5 ml / 10 kg lg.
Adult cattle	40-50 ml
Calf	0.5-1 ml / 10 kg lg.
Things	2-4 ml
Beer	1-2 ml
Lam	0.3-0.5 ml / 10 kg lg.
Sheep	1-2 ml / 10 kg lg.
Goat	0.5-1 ml / 10 kg lg.
Laying hens: start and growth	180-200 ml / 1 000 animals
Laying hens: in production	80-100 ml / 1 000 animals
Broilers	80-100 ml / 1 000 animals

Vitamin deficiencies can be treated with the recommended dosages mentioned above. Then adapted feed should be administered, provided with adapted vitamin amounts.

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

Since the fat-soluble vitamins are stored in the body and are only absorbed slowly metabolized, toxicity is more likely to be chronic in nature and symptoms of overdose (hypervitaminosis) appear after repeated administration of high doses. Overdose is more likely to be chronic in nature and symptoms therefore usually only occur after repeated administration of high doses. The amount of vitamin A necessary to obtain toxic effects is in most cases animal species 10 to 1000 times the normal dietary requirement. Possible symptoms of acute overdose include general malaise, anorexia, nausea, skin peeling, weakness, tremor, convulsions and paralysis. Hypervitaminosis A manifests as symptoms

similar to those of deficiency: lethargy, colic, joint pain, crumbly hooves and dry, flaky skin, accelerated ossification of the epiphyseal cartilage of the long bones. Hypervitaminosis D causes calcium deposits in the soft tissues and blood vessel walls accompanied proceeding with a demineralization of the bone tissue. Hypervitaminosis E causes, among other things, coagulation disorders, reduced growth and abnormal bone calcification."

The assumed maximum safe long-term vitamin D dosage for long-term absorption amounts to four to ten times the normal nutritional requirement. Hypervitaminosis D symptoms include vomiting, depression, polyuria, polydipsia and hyperphosphatemia followed by hypercalcemia and acute kidney failure. As for vitamin E, most studies have shown that it is relatively non-toxic. The toxicity of vitamin E is rather low: in most animal species the lowest toxic dose is approximately 1000 times the normal nutritional requirement.

4.11 Specific restrictions on use and special conditions of use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products to reduce the risk of development of resistance

Not applicable.

4.12. Withdrawal period:

(Organ) Meat: 28 days.

Milk: 0 day.

Horse: Not Applicable

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Vitamins.

ATC-vet 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 can lead to a wide range of conditions related to the aforementioned processes: In cattle, a deficiency can lead to reduced feed intake, retarded growth, nyctalopia, xerophthalmia, lacrimation, diarrhea, reproductive abnormalities, and increased susceptibility to infections. Similar symptoms occur in sheep, as well as changes in wool structure and strength. Poultry shortages also reduce egg production and hatchability. Horses develop eye lesions and visual abnormalities similar to those in ruminants, reproductive disorders, anorexia, and progressive weakness.

Vitamin D is primarily involved in the regulation of parathyroid hormone secretion and the regulation of calcium and phosphorus metabolism, which are 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 primarily 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, primarily with palmitate, and taken up by chylomicrons, before being transported to the liver via the lymphatic system. The liver contains approximately 90% of the total vitamin A in the body.

Vitamin A is excreted mainly through urine and feces.

Vitamin D is absorbed along with existing fats and is therefore stimulated by bile and pancreatic secretions. Absorbed vitamin D is taken up by chylomicrons along with other fats for transport via the lymphatic system into 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 primarily in the feces with the help of bile salts. Very little vitamin D appears in the urine.

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

6. PHARMACEUTICAL INFORMATION

6.1 Excipients:

Polysorbate 80
Propylene glycol
Sodium methyl parahydroxybenzoate
Water.

6.2 Incompatibilities

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

Vitamin A is also incompatible with copper and cobalt salts, light and heat.

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 at below 25°C.

Protect from Heat, light & 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 Can is closed with Plastic Cap with induction sealed.

Pack sizes: 100 ml, 500ml & 1 liter

**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.: 058991

9. DATE OF FIRST AUTHORISATION

Date of Reg: 28-08-2009

10. DATE OF REVISION OF THE TEXT

17-02-2025

MANUFACTURED BY:



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