For Veterinary Use Only

iksir® AD_3E

Solution for Injection
Veterinary Vitamin

COMPOSITION

It is a light yellow oily solution comprising 400,000 IU Vitamin A palmitate, 75,000 IU Vitamin D_3 (cholecalciferol), and 50 mg Alfa-tocopherol acetate per ml.

PHARMACOLOGICAL PROPERTIES

Iksir AD_3E Solution for Injection is a vitamin combination consisting of fat soluble vitamins A, D, and E at higher concentrations as dissolved in lipid-based carrier medium. Vitamin A administered through intramuscular or subcutaneous injection is moved to liver in ester-form (oleic, steraic linoleic esters but mainly palmitic ester via lymph. A considerable storage is generated in kidneys, lipid stores, adrenal glands, ovaries and mammary glands as well as liver. Although vitamin A is stored very quickly in liver, its half-life to be released into the blood is around 50 days. Vitamin A is excreted through gaita and urination as biotransformation products.

Vitamin D3 cholecalciferol is formed as a result of 7- dehydrocholesterol shaped from cholesterol in animal tissues being exposed to ultraviolet light. Half life of active D3 metabolyte is around 3-5 days.

Vitamin E is a common name for 6-chromonal derivatives including at least 8 different natural tocopherols which are biologically efficient. 90% of vitamin E in animal tissues comprises d-alfatocopherol. All natural tocopherols consist of d isomer, and is more efficient. Plasm vitamin E concentration in animals is around 1.5 mcg/ ml. Liver concentrations is two fold more than plasma concentrations. Its density in musculoskeletal is half of plasma density.

AREA OF USE/INDICATIONS

It is used in lower productivity, growth and improvement cases caused by lack of vitamins; in order to improve ability of benefiting from feed and accelerate improvements in fatlings; to correct negative effects depending on immobility in animals to which closed feeding is administered; to develop wool productivity and quality; to improve resistance to inappropriate environment and climate conditions; in visual impairments and blindness caused by lack of vitamin; foot stickings, paralysis and lameness; wool and hair loss; to fulfil increased need for vitamin in pregnancy and lactation; as supportive to main therapy in non-regular estrous and non-fertilized cases; bone diseases including rachitism and osteomalacia; as supportive in walking difficulties and muscle anomalies; to improve body resistance in recovery periods; in conditions preventing vitamin A synthesis from carotene because of diarrhoea and various diseases; to prevent animals to be affected negatively in workplaces in which low nutritive or nitrate-rich fertilizers and pesticides are used, or in which intensive breeding is performed with grazing lands without fresh grass.

USAGE AND DOSAGE:

Iksir AD_3E Solution for Injection is **administered intramuscularly through <u>neck area</u> in cattle, horse, sheep, and goats.**

As therapy dose;

Cow-Bull		3 – 6 ml
Horse		3 ml
Calf-Foal		0.5 – 1 ml
Sheep-goat		1 ml
Lamb-Yean	:	0.25 – 0.5 ml
Rabbit		0.1 – 0.25 ml

Specified doses are repeated at 2 month intervals.

SPECIFIC CLINICAL PARTICULARS AND SPECIAL WARNINGS FOR TARGET SPECIES:

Vitamin content is provided to be absorbed easily through injection area and to be dispersed in intertissue liquid because of hydrodispersible and liposoluble structure of Iksir AD_3E Solution for Injection. Thus it is benefited from vitamins A, D_3 and E in a short time and at higher level, and they are stored in liver, muscle, and lipid tissues. Because there is no accumulation risk around injection area it doesn't cause complications in administration area. It is recommended to be administered 7-8 weeks before breeding period in breeding animals. It supports baby to be grown healthier when administered during last 1/3 of pregnancy period.

UNDESIRED/SIDE EFFECTS

A little puffiness which is recovered in a short time may be occurred around injection area. When giving vitamin D_3 at higher doses and for a while, it may cause released Ca and P from bones, and consequently calcification on some soft tissue and organs. When using vitamin A excessively it may cause hypervitaminosis.

DRUG INTERACTIONS:

No incompatibility with any drug is known.

WARNINGS ON DRUG RESIDUES IN FOOD:

Withholding Period (WHP): It is zero (0) days for meat and milk during treatment and after the final drug administration.

CONTRAINDICATIONS:

No side-effects at recommended doses.

GENERAL WARNINGS:

Consult your veterinary surgeon before using and in case an undesired effect is observed. Keep out of reach of children. Read package insert before using. Avoid buying expired products or the ones with open package.

STORAGE CONDITIONS AND SHELF LIFE:

The product should be stored at room temperature (15 – 25 ^{o}C) and should be protected from light. Shelf life is 2 years (24 months)**.**

DISPOSAL AFTER USE AND WARNINGS FOR NON-TARGET SPECIES:

The drug with expired shell life, which is opened or kept for a long time without complying with storage conditions should be disposed together with inner package (bottle).

COMMERCIAL PRESENTATION FORM :

Offered for sale as 20, 50, and 100 ml, and as 250 ml amber glass vials in cardboard box packages.

PLACE AND CONDITIONS OF SALE:

Sold with Veterinary Surgeon prescription in pharmacies and veterinary surgeries (VSP).

APPROVAL DATE OF PACKAGE INSERT: 28.04.2009

MARKETING AUTHORIZATION DATE AND NO. 10.03.2006-15/079

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

Alke Sağlik Ürünleri San. ve Tic. A.Ş

Dolayoba, Çınardere Mh. 3. Petek Sk.

No: 18, 34896 Pendik-ISTANBUL

NAME AND ADDRESS OF MANUFACTURER COMPANY:

Alke Sağlik Ürünleri San. ve Tic. A.Ş

Merkez Organize Sanayi Bölgesi 2. Kısım 10. Cadde No:7 Tokat