BELAVIT AD$_3$E

Solution for injection for horses, cattle, pigs, and dogs

DATA SHEET

INDICATIONS

Treatment of combined vitamin A, vitamin D, and vitamin E deficiencies.

BENEFITS

- Can be used in cattle, horses, pigs and dogs
- For subcutaneous or intramuscular use

LIST No	UNIT PACKAGE	CASE SIZE
1VIT024	100 ml	6

See reverse for Administration & Dosage

Belavit AD$_3$E

Solution for injection for horses, cattle, pigs, and dogs

PRESENTATION
A clear, yellow solution for injection. 1 ml contains the active substances:
- Retinol palmitate 176.47 mg (equivalent to 300,000 I.U. Vitamin A)
- All-rac alpha tocopheryl acetate 50.00 mg (equivalent to 45.56 mg alpha-tocopherol - Vitamin E)
- Oily solution of cholecalciferol 100.00 mg (contains 2.5 mg cholecalciferol; equivalent to 100,000 I.U. Vitamin D$_3$)

USES
Treatment of combined vitamin A, vitamin D, and vitamin E deficiencies in cattle, horses, pigs and dogs.

DOSAGE AND ADMINISTRATION
For subcutaneous or intramuscular use as a single administration.

Vitamin AD$_3$E injection as a single injection per animal:

Cattle	5	ml
Horse	2-4	ml
Calf	2	ml
Pig	1	ml
Weaned piglet	0.2-0.4	ml
Piglet	0.1-0.2	ml
Dog	0.05-0.3	ml

The proposed injection volumes correspond to the following concentrations of vitamins:

Target animal species	Injection volume	Vitamin A	Vitamin D$_3$	Vitamin E
Horse (500kg)	2.5ml	1500 IU/kg bw	500 IU/kg bw	0.25 mg/kg bw
Cattle (500kg)	5ml	3000 IU/kg bw	1000 IU/kg bw	0.5 mg/kg bw
Calf (100kg)	2ml	6000 IU/kg bw	2000 IU/kg bw	1.0 mg/kg bw
Pig (100kg)	1ml	3000 IU/kg bw	1000 IU/kg bw	0.5 mg/kg bw
Weaned piglet (40kg)	0.4ml	3000 IU/kg bw	1000 IU/kg bw	0.5 mg/kg bw
Piglet (10kg)	0.1ml	3000 IU/kg bw	1000 IU/kg bw	0.5 mg/kg bw
Dog (30kg)	0.2ml	2000 IU/kg bw	667 IU/kg bw	0.33 mg/kg bw

WITHDRAWAL PERIOD(S)
Cattle:
Meat and offal: 50 days
Milk: 0 hours

Horse:
Meat and offal: 50 days
Not authorised for use in horses producing milk for human consumption.

Pig:
Meat and offal: 20 days

PHARMACODYNAMIC PROPERTIES
Vitamin A (Retinol)
As a fat-soluble vitamin, vitamin A belongs to those vitamins, which affect (like steroid hormones) gene expression. It is essential for growth, cell differentiation, reproduction of male and female animals, vision, bone development and the immune response.
Both deficiency and excess may cause severe dysfunction of these processes. Vitamin A homeostasis in plasma is tightly controlled. Abnormal plasma levels may therefore only be detected in case of extreme high or extreme low vitamin A availability. Liver biopsy may provide more accurate information on the vitamin A status of an animal.
The liver is of central importance in vitamin A metabolism and serves as the major vitamin A reservoir.
Vitamin D$_3$ (Cholecalciferol)
As a fat-soluble vitamin, vitamin D belongs to those vitamins, which affect (like steroid hormones) gene expression. Vitamin D is essential for regulation of calcium metabolism. In most animal species, especially in poultry, Vitamin D$_3$ possesses a stronger activity than vitamin D$_2$ (ergocalciferol).
Vitamin E (α-Tocopherol)
Vitamin E belongs to the group of fat-soluble vitamins. The tocopherols are important physiological antioxidants. Vitamin E protects the unsaturated fatty acids (e.g. lipids of the cytoplasmic and mitochondrial membranes) against oxidation.
Besides its importance as antioxidant, vitamin E stimulates the formation of prostaglandin E from arachidonic acid and hinders blood coagulation. In its protective function for leucocytes and macrophages, it ensures phagocytosis and stimulates the immune response.
Vitamin E deficiency may cause nutritional diseases such as muscle dystrophy, exudative diathesis, encephalomalacia, and liver necrosis.
An excess of unsaturated fatty acids supports vitamin E deficiency symptoms.

PHARMACOKINETIC PARTICULARS
Vitamin A
Following a single parenteral administration of 1 x 106 I.U. in cattle, an increase in vitamin A plasma values is observed. In animals provided with sufficient vitamin A, the plasma values increase from 160 ± 37 to 8641 ± 1593 µg/l within 2 days and return to their basic values within 8 days. Vitamin A is transported to the liver, where it is stored. Excretion occurs in form of the glucuronide with the bile. In the small intestines the molecule is de-glucuronidated and vitamin A is absorbed once again (enterohepatic circulation). A fraction of vitamin A is excreted with the urine.
Vitamin D$_3$ (Cholecalciferol)
Vitamin D$_3$ is transported via the lymph to the liver, where it is hydroxylated to form the biologically active hydroxy compounds. In the kidneys 1,25- and 24,25 Dihydroxyvitamin D$_3$ are formed. 1,25-Dihydroxy-Vitamin D$_3$ (Calcitriol) shows the highest biological efficacy.
Vitamin E (α-Tocopherol)
Following parenteral administration vitamin E is distributed via the lymph into systemic circulation and peak plasma levels are obtained after 4 to 9 hours. In the blood vitamin E is mainly bound to β–lipo-proteins. Vitamin E accumulates in the liver, cardiac muscle, in fat tissue and the adrenal gland. The majority of vitamin E is excreted by the liver with the bile, the remaining with the urine.

CONTRAINDICATIONS
Treatment with **Belavit AD$_3$E** is contraindicated in cases of hypervitaminosis.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
The recommended dose and duration of treatment should not be exceeded.
The use of intramuscular lipid-soluble vitamin products in horses may increase the risk of myositis and myonecrosis.

IN CASE OF ACCIDENTAL SELF-INJECTION IN HUMANS
A risk of hypervitaminosis in relation to vitamin A cannot be excluded. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. Studies with vitamin A in laboratory animals have shown evidence of teratogenic effects. Therefore, this product should not be administered by pregnant women.

This product may cause irritation of eyes and skin. Contact with eyes and skin should be avoided and any accidental spillage onto the eyes or skin should be rinsed off with water immediately.
This product may cause hypersensitivity (allergic) reactions in sensitised people. People with known hypersensitivity to any of the active substances should avoid contact with the product. If you develop symptoms such as a rash after accidental exposure, seek medical advice and show the physician this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention. Wash hands after use.

ADVERSE REACTIONS
A temporary swelling at the injection site may occur. In rare cases anaphylactic reactions may be observed (more than 1 but less than 10 animals in 10,000 animals treated).

USE DURING PREGNANCY OR LACTATION
There are indications of teratogenic effects of high doses of vitamin A in humans and laboratory animals. The safety of the veterinary medicinal product has not been established during pregnancy and lactation in the target species. Therefore, use only according to the benefit/risk assessment by the responsible veterinarian.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTIONS
None known.

OVERDOSE
A substantial overdose of vitamin A is related to the risk of intoxication (hypervitaminosis). Symptoms of acute vitamin A - intoxication include sleepiness, motor disorders, vomiting, and squamous skin degeneration. Following an overdose in pregnant animals, especially in the early stage of gestation, an increase in foetal absorption, stillbirths and malformations may be observed.
The main effect of a vitamin D hypervitaminosis is hypercalcaemia with associated symptoms including organ calcification and renal and cardiovascular damage.

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

EXCIPIENTS
Medium-chain triglycerides
DL-alphatocopherol (E307)

SHELF LIFE
Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 28 days

SPECIAL PRECAUTIONS FOR STORAGE
Do not store above 30 °C.
The stopper can be punctured up to 50 times.

DISPOSAL
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

MARKETED IN UK BY
Bimeda UK
Unit 2, Bryn Cefni Industrial Park,
Llangefni, Anglesey, Wales, LL777XA.
Phone: +44 (0) 1248 725 400

MARKETING AUTHORISATION NUMBER
Vm 41816/4004

DISTRIBUTION CATEGORY
POM – V

Prescription-only medicine – Veterinarian
Use Medicines Responsibly

TAKE TIME  OBSERVE LABEL DIRECTIONS

www.bimeda.co.uk

Bimeda data sheet created: October 2020