ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE PACKAGE

Cardboardboxes with 1, 6 or 12 vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Belavit AD_3E**,** solution for injection for horses, cattle, pigs, and dogs

Retinol palmitate, all-rac alpha tocopheryl acetate, cholecalciferol

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml solution contains:

Active substance:

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)	

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

1 x 100 ml
6 x 100 ml
12 x 100 ml

5. TARGET SPECIES

Cattle, horses, pigs and dogs.

6. INDICATION(S)

[Not applicable]

7. METHOD AND ROUTE(S) OF ADMINISTRATION

This veterinary medicinal product should not be used by subcutaneous route of administration in food producing species.
For intramuscular use in horses, cattle and pigs.
For subcutaneous or intramuscular use in dogs.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):

Cattle:	meat and offal:	259 days
	milk:	120 hours (5 days)
Horse:	meat and offal:	250 days

Not authorised for use in horses producing milk for human consumption.

Pig:	meat and offal:	194 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 28 days
Once opened use by…

11. SPECIAL STORAGE CONDITIONS

Do not store above 30 °C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bela-Pharm GmbH & Co. KG
Lohner Strase 19
49377 Vechta
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 41816/4004

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial of 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Belavit AD_3E**,** solution for injection for horses, cattle, pigs, and dogs

Retinol palmitate, all-rac alpha tocopheryl acetate, cholecalciferol

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml solution contains:

Active substance:

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)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle, horses, pigs and dogs.

6. INDICATION(S)

[Not applicable]

7. METHOD AND ROUTE(S) OF ADMINISTRATION

This veterinary medicinal product should not be used by subcutaneous route of administration in food producing species.
For intramuscular use in horses, cattle and pigs.
For subcutaneous or intramuscular use in dogs.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):

Cattle:	meat and offal:	259 days
	milk:	120 hours (5 days)
Horse:	meat and offal:	250 days

Not authorised for use in horses producing milk for human consumption.

Pig:	meat and offal:	194 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 28 days
Once opened use by…

11. SPECIAL STORAGE CONDITIONS

Do not store above 30 °C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Not requested on the immediate label

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bela-Pharm GmbH & Co. KG
Lohner Strase 19
49377 Vechta
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm41816/4004

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Vitamin AD_3E pro injectione, solution for injection for horses, cattle, pigs, and dogs.

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

Bela-Pharm GmbH & Co. KG
Lohner Strase 19
49377 Vechta
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Belavit AD_3E, solution for injection for horses, cattle, pigs, and dogs

Retinol palmitate, all-rac alpha tocopheryl acetate and cholecalciferol

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1 ml solution for injection contains:

Active substance:

Retinol palmitate (equivalent to 300,000 I.U. Vitamin A)	176.47 mg
all-rac alpha tocopheryl acetate (equivalent to 45.56 mg alpha-tocopherol) (Vitamin E)	50.00 mg
Oily solution of cholecalciferol (contains 2.5 mg cholecalciferol; equivalent to 100,000 I.U. Vitamin D_3)	100.00 mg

Clear, yellow solution

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use in food producing animals with adequate vitamin A supply due to the possibility of
accumulation in edible tissues.
The treatment with Vitamin AD_3E is contraindicated in case of a hypervitaminosis.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

A temporary swelling at the injection site may occur. In rare cases anaphylactic reactions may be observed.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle, horses, pigs and dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

This veterinary medicinal product should not be used by subcutaneous route of administration in food producing species.
For intramuscular use in horses, cattle and pigs.
For subcutaneous or intramuscular use in dogs.

Vitamin AD_3E pro injectione 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 (500 kg)	2.5 ml	1500 IU/kg bw	500 IU/kg bw	0.25 mg/kg bw
Cattle (500 kg)	5 ml	3000 IU/kg bw	1000 IU/kg bw	0.5 mg/kg bw
Calf (100 kg)	2 ml	6000 IU/kg bw	2000 IU/kg bw	1.0 mg/kg bw
Pig (100 kg)	1 ml	3000 IU/kg bw	1000 IU/kg bw	0.5 mg/kg bw
Weaned piglet (40 kg)	0.4 ml	3000 IU/kg bw	1000 IU/kg bw	0.5 mg/kg bw
Piglet (10 kg)	0.1 ml	3000 IU/kg bw	1000 IU/kg bw	0.5 mg/kg bw
Dog (30 kg)	0.2 ml	2000 IU/kg bw	667 IU/kg bw	0.33 mg/kg bw

For single administration.
The stopper could be punctured up to 50 times.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIOD(S)

Cattle: meat and offal: 259 days
milk: 120 hours (5 days)

Horse: meat and offal: 250 days
Not authorised for use in horses producing milk for human consumption.

Pig: meat and offal: 194 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 30 °C.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days

12. SPECIAL WARNING(S)

Special warnings for each target species:
None.

Special precautions for use in animals
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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

- In case of accidental self-injection, a risk of hypervitaminosis in relation to vitamin A cannot be excluded. Therefore, administration should be performed with great caution. 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.

Pregnancy and 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 interaction:
None known.

Overdose (symptoms, emergency procedures, antidotes):
A substantial overdose of vitamin A is related to the risk of intoxication (hypervitaminosis). Symptoms of acute vitamin A intoxication include somnolence, motoric disorders, vomiting, and squamous skin degeneration. Following an overdose in pregnant animals, especially in the early stage of gestation, an increase number of 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.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.
UK: Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2021

15. OTHER INFORMATION

1 x 100 ml
6 x 100 ml
12 x 100 ml

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved: 23/12/21