

**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

{Label}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Vigophos 100 mg / ml + 0.05 mg / ml solution for injection for cattle  
butafosfan, cyanocobalamin

**2. STATEMENT OF ACTIVE SUBSTANCES**

1 ml contains:

**Active substances:**

Butafosfan	100.00 mg
Cyanocobalamin	0.05 mg

**3. PHARMACEUTICAL FORM**

Solution for injection

**4. PACKAGE SIZE**

100 ml

**5. TARGET SPECIES**

Cattle

**6. INDICATION(S)**

Read the package leaflet before use.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For intravenous use.

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD (S)**

Withdrawal period(s):

Cattle:

Meat and offal: zero days

Milk: zero hours

**9. SPECIAL WARNING(S), IF NECESSARY**

**10. EXPIRY DATE**

EXP {month/year}

Shelf-life after first opening of the immediate packaging: 28 days

Once opened use by.....

**11. SPECIAL STORAGE CONDITIONS**

Keep the vial in the outer carton in order to protect from light.

**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**

Livisto Int'l, S.L.  
Av. Universitat Autònoma, 29  
08290 Cerdanyola del Vallès (Barcelona)  
Spain

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 43173/4008

**17. MANUFACTURER'S BATCH NUMBER**

Batch {number}

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

{Carton }

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Vigophos 100 mg / ml + 0.05 mg / ml solution for injection for cattle  
butafosfan, cyanocobalamin

**2. STATEMENT OF ACTIVE SUBSTANCES**

1 ml contains:

**Active substances:**

Butafosfan	100.00 mg
Cyanocobalamin	0.05 mg

**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

**6. INDICATION(S)**

Read the package leaflet before use.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For intravenous use.

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD (S)**

Withdrawal period(s):

Cattle:

Meat and offal: zero days

Milk: zero hours

**9. SPECIAL WARNING(S), IF NECESSARY**

**10. EXPIRY DATE**

EXP {month/year}

Shelf-life after first opening of the immediate packaging: 28 days

Once opened use by.....

**11. SPECIAL STORAGE CONDITIONS**

Protect from light.

**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**

Livisto Int'l, S.L.  
Av. Universitat Autònoma, 29  
08290 Cerdanyola del Vallès (Barcelona)  
Spain

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 43173/4008

**17. MANUFACTURER'S BATCH NUMBER**

Batch {number}



**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**

Vigophos 100 mg / ml + 0.05 mg / ml solution for injection for cattle

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

Marketing authorisation holder:

Livisto Int'l, S.L.  
Av. Universitat Autònoma, 29  
08290 Cerdanyola del Vallès (Barcelona)  
Spain

Manufacturers responsible for batch release:

aniMedica GmbH  
Im Südfeld 9  
48308 Senden-Bösensell  
Germany

aniMedica Herstellungs GmbH  
Im Südfeld 9  
48308 Senden-Bösensell  
Germany

Industrial Veterinaria, S.A.  
Esmeralda 19  
Esplugues de Llobregat  
08950 Barcelona  
Spain

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Vigophos 100 mg / ml + 0.05 mg / ml solution for injection for cattle  
butafosfan, cyanocobalamin

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

1 ml contains:

**Active substances:**

Butafosfan	100.00 mg
Cyanocobalamin	0.05 mg

**Excipients:**

Benzyl alcohol (E1519)	10.00 mg
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Clear, reddish to red solution.

**4. INDICATION(S)**

For the supportive treatment of secondary ketosis (e.g in abomasal displacement).

## **5. CONTRAINDICATIONS**

None.

## **6. ADVERSE REACTIONS**

None known.

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.

## **7. TARGET SPECIES**

Cattle

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

For intravenous use

Cattle: 5 mg of butafosfan and 2.5 µg of cyanocobalamin per kg bodyweight (bw) corresponding to 5 ml / 100 kg bw daily with an 24 hour interval for three consecutive days.

## **9. ADVICE ON CORRECT ADMINISTRATION**

Not applicable.

## **10. WITHDRAWAL PERIOD(S)**

Cattle:

Meat and offal: zero days

Milk: zero hours

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Keep the vial in the outer carton in order to protect from light.

Shelf-life after first opening of the immediate packaging: 28 days

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.

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the vial should be discarded should be worked out. This discard date should be written in the space provided.

## **12. SPECIAL WARNING(S)**

### Special warnings for each target species:

None.

### Special precautions for use in animals:

Not applicable.

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

People with known hypersensitivity to any of the ingredients should avoid contact with the product.

The product might be mildly irritating to the skin or the eye. Dermal and ocular exposure should therefore be avoided. In case of exposure rinse the skin and/or the eye with water.

### Pregnancy and lactation:

No negative effects on the use of the product during pregnancy or lactation have been reported. Can be used during pregnancy and lactation.

### Interaction with other medicinal products and other forms of interaction:

None known.

### Overdose (symptoms, emergency procedures, antidotes:

None known.

### 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**

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**

**15. OTHER INFORMATION**

Pack sizes:

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

Not all pack sizes may be marketed.

To be supplied only on veterinary prescription.

Approved 27 July 2022

A handwritten signature in black ink, appearing to be 'M. M. M.', located below the approval date.