

**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

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

**Active substances:**

Butafosfan	100 mg
Cyanocobalamin (vitamin B <sub>12</sub> )	0.05 mg

**3. PACKAGE SIZE**

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

**4. TARGET SPECIES**

Cattle, horses, dogs

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Cattle and horses:  
Intravenous use.

Dogs:  
Intravenous, intramuscular and subcutaneous use.

**7. WITHDRAWAL PERIODS**

Withdrawal period:

Cattle and horses:

Meat and offal:	Zero days.
Milk:	Zero hours.

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached, use within 28 days – by.....

**9. SPECIAL STORAGE PRECAUTIONS**

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

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

Industrial Veterinaria SA

**14. MARKETING AUTHORISATION NUMBERS**

Vm 36547/5005

Vm 36547/3005

**15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**  
**{Label, bottle, 100 ml}**

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

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

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

**Active substances:**

Butafosfan	100 mg
Cyanocobalamin (vitamin B <sub>12</sub> )	0.05 mg

**3. TARGET SPECIES**

Cattle, horses, dogs

**4. ROUTES OF ADMINISTRATION**

Cattle and horses:

Intravenous use.

Dogs:

Intravenous, intramuscular and subcutaneous use.

Read the package leaflet before use.

**5. WITHDRAWAL PERIODS**

Withdrawal period:

Cattle and horses:

Meat and offal: Zero days.

Milk: Zero hours.

**6. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached use within 28 days - by....

**7. SPECIAL STORAGE PRECAUTIONS**

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

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

Industrial Veterinaria SA

**9. BATCH NUMBER**

Lot {number}

## **PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

### **PACKAGE LEAFLET**

#### **1. Name of the veterinary medicinal product**

Vigophos 100 mg / ml + 0.05 mg / ml solution for injection for cattle, horses and dogs

#### **2. Composition**

Each ml contains:

##### **Active substances:**

Butafosfan	100 mg
Cyanocobalamin (vitamin B <sub>12</sub> )	0.05 mg

##### **Excipients:**

Benzyl alcohol (E1519)	10.0 mg
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Clear, reddish to red solution.

#### **3. Target species**

Cattle

Horses

Dogs

#### **4. Indications for use**

All target species:

- Supportive treatment and prevention of hypophosphatemia and/or cyanocobalamin (vitamin B<sub>12</sub>) deficiency.

Cattle:

- Supportive treatment to restore rumination following surgical treatment of displaced abomasum associated with secondary ketosis.
- Complementary treatment of parturient paresis in addition to Ca/Mg therapy.
- Prevention of ketosis development, if administered before calving.

Horses:

- Adjunctive therapy in horses suffering from muscular exhaustion.

#### **5. Contraindications**

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

## **6. Special warnings**

### Special precautions for safe use in the target species:

Intravenous administration should be done very slowly since cases of circulatory shock may be

associated with too rapid injection.

In dogs suffering from chronic renal insufficiency the veterinary medicinal product should only be used according to the benefit-risk assessment by the responsible veterinarian.

### 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 veterinary medicinal product.

This veterinary medicinal product may cause skin and eye irritation. Avoid contact with skin and eyes. In case of accidental exposure, rinse the affected area thoroughly with water.

Self-injection should be avoided. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

### Pregnancy and lactation:

Can be used during pregnancy and lactation in cows.

The safety of the veterinary medicinal product has not been established during pregnancy and

lactation in mares and bitches. Laboratory studies in rats have not produced any evidence of terato-genic, foetotoxic or maternotoxic effects. 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:

No adverse effect was reported after intravenous administrations up to 5 times the recommended dose in cattle.

Except transient slight swelling at the injection site, no other adverse effect was reported after subcutaneous administrations up to 5 times the recommended dose in dogs.

No overdose data are available for dogs after intravenous and intramuscular administrations.

No overdose data are available for horses

### Major incompatibilities:

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

## 7. Adverse events

Cattle, horses and dogs:

Rare (1 to 10 animals / 10,000 animals treated):
Injection site pain <sup>1</sup>
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Circulatory shock <sup>2</sup>

<sup>1</sup>Has been reported following subcutaneous administration in dogs.

<sup>2</sup>In cases where rapid intravenous infusion has occurred.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at <https://www.gov.uk/report-veterinary-medicine-problem>.

## 8. Dosage for each species, routes and method of administration

Cattle and horses:  
Intravenous use.

Dogs:  
Intravenous, intramuscular and subcutaneous use.

The dose depends on the animal's body weight (bw) and condition.

Species	Dose butafosfan (mg/kg bw)	Dose cyanocobalamin (mg/kg bw)	Dose volume of the veterinary medicinal product	Route of administration
Cattle Horses	5–10	0.0025-0.005	5–10 ml/100 kg	i.v.
Dogs	10–15	0.005–0.0075	0.1–0.15 ml/kg	i.v., i.m., s.c.

For the supportive treatment of secondary ketosis in cows, the recommended dose should be administered on three consecutive days.

For the prevention of ketosis in cows, the recommended dose should be administered on three consecutive days within the period of 10 days before expected calving.

For other indications, treatment should be repeated as necessary.

## **9. Advice on correct administration**

It is recommended that the solution is warmed to body temperature before administration.

The stopper may be safely punctured up to 50 times with a needle-size not exceeding 18 G. For multiple bottle entry, an aspirating needle or multi-dose syringe is recommended to avoid excessive broaching of the stopper.

## **10. Withdrawal periods**

Cattle and horses:

Meat and offal: Zero days.

Milk: Zero hours.

## **11. Special storage precautions**

Keep out of the sight and reach of children.

Keep the bottle 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 after Exp. The expiry date refers to the last day of that month.

## **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES**

Vm 36547/5005

Vm 36547/3005

Pack sizes:

Cardboard box containing 1 x 100 ml, 6 x 100 ml or 12 x 100 ml

Not all pack sizes may be marketed.

## 15. PID LINK (Do not print heading)

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

## 16. Contact details

### Marketing authorisation holder:

Industrial Veterinaria SA  
Calle Esmeralda, 19  
08950 Esplugues de Llobregat  
Spain

### Manufacturer 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

08950 Esplugues des Llobregat (Barcelona)

Spain

### Local representatives and contact details to report suspected adverse reactions:

FORTE Healthcare Limited,

Block 3, Unit 9,

CityNorth Business Campus,

Stamullen, Co.

Meath. K32 D990

Republic of Ireland

Tel.: +353 1 841 7666

E-Mail: [pharmacovigilance@fortehealthcare.com](mailto:pharmacovigilance@fortehealthcare.com)

## 17. Other information

POM-V

Veterinary medicinal product subject to prescription

*Gavin Hall*

Approved: 19 November 2025