

## PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butasal 100 mg/ml + 0.05 mg/ml Solution for Injection for Horses, Cattle, Dogs and Cats

butafosfan

cyanocobalamin (vitamin B12)

### 2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:

Butafosfan	100.0 mg
Cyanocobalamin (vitamin B12)	0.05 mg

### 3. PHARMACEUTICAL FORM

Solution for injection.

### 4. PACKAGE SIZE

1x100 ml

6x100 ml

### 5. TARGET SPECIES



Horses, cattle, dogs, cats.

### 6. INDICATION(S)

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

Cattle, horses: for intravenous use.

Dogs, cats: for intravenous, intramuscular, subcutaneous use.

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)**

Withdrawal period:

Cattle, horses:

Meat and offal: zero days.

Milk: zero hours.

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

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP:

Once broached: use within 28 days.

The cap may be safely punctured up to 15 times.

**11. SPECIAL STORAGE CONDITIONS**

Do not store above 25 °C.

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**

Dispose of waste material in accordance with local requirements.

**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. Administration by a veterinary surgeon or under their direct responsibility.

**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**

Interchemie Werken De Adelaar Eesti AS  
Vanapere tee 14  
Püünsi Village  
Viimsi Rural Municipality  
Harju County 74013  
Estonia

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

Vm 51467/4002

<b>17. MANUFACTURER'S BATCH NUMBER</b>
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Batch number:

## **PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**100 ml amber glass vial**

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

Butasal 100 mg/ml + 0.05 mg/ml Solution for Injection for Horses, Cattle, Dogs and Cats  
butafosfan  
cyanocobalamin (vitamin B12)

### **2. STATEMENT OF ACTIVE SUBSTANCES**

1 ml contains:  
Butafosfan 100.0 mg  
Cyanocobalamin (vitamin B12) 0.05 mg

### **3. PHARMACEUTICAL FORM**

Solution for injection.

### **4. PACKAGE SIZE**

100 ml.

### **5. TARGET SPECIES**



Horses, cattle, dogs, cats.

### **6. INDICATION(S)**

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

Cattle, horses: for intravenous use.  
Dogs, cats: for intravenous, intramuscular, subcutaneous use.  
Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)**

Withdrawal period:

Cattle, horses:

Meat and offal: zero days

Milk: zero hours

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

Read the package leaflet before use.

**10. SPECIAL STORAGE CONDITIONS**

EXP:

Once broached: use within 28 days. The cap may be safely punctured up to 15 times.

Once broached, use by: \_\_\_\_\_.

**11. SPECIAL STORAGE CONDITIONS**

Do not store above 25 °C.

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

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

Dispose of waste material in accordance with local requirements.

**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. Administration by a veterinary surgeon or under their direct responsibility.

**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**

Interchemie Werken De Adelaar Eesti AS  
Vanapere tee 14  
Püünsi Village  
Viimsi Rural Municipality  
Harju County 74013  
Estonia

<b>16. MARKETING AUTHORISATION NUMBER(S)</b>
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Vm 51467/4002

<b>17. MANUFACTURER'S BATCH NUMBER</b>
--

Batch number:

## PACKAGE LEAFLET

### Butasal 100 mg/ml + 0.05 mg/ml Solution for Injection for Horses, Cattle, Dogs and Cats

#### 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:

Interchemie Werken De Adelaar Eesti AS

Vanapere tee 14

Püünsi Village

Viimsi Rural Municipality

Harju County 74013

Estonia

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

Butasal 100 mg/ml + 0.05 mg/ml Solution for Injection for Horses, Cattle, Dogs and Cats

butafosfan

cyanocobalamin (vitamin B12)

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

Each ml of the solution for injection contains:

##### Active substances:

Butafosfan	100.0 mg
Cyanocobalamin (vitamin B12)	0.05 mg

##### Excipients:

Benzyl alcohol (E1519)	10.5 mg
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Clear red solution without visible particles.

#### 4. INDICATION(S)

As supportive treatment of metabolic or reproductive disorders, when supplementation of phosphorous and cyanocobalamin is needed.

In case of peri-parturient (period immediately before and after calving) metabolic disorders, tetany (intermittent muscular spasms) and paresis (milk fever), the product should be administered in addition to magnesium and calcium, respectively.

## 5. CONTRAINDICATIONS

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

## 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.

Alternatively, you can report via your national reporting system: *To be completed in accordance with national requirements after conclusion of the MR phase.*

## 7. TARGET SPECIES

Horses, cattle, dogs, cats.

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

Route of administration:

Cattle, horses: for intravenous (i.v.) use

Dogs, cats: for intravenous (i.v.), intramuscular (i.m.), subcutaneous (s.c.) use

Dose:

Target species/ sub-category	Butafosfan (mg/kg)	Vitamin B12 (µg/kg)	The product (ml/kg)
Horses	2.0 – 5.0	1.0 – 2.5	0.02 – 0.05
Foals	3.3 – 5.6	1.65 – 2.8	0.033 – 0.056
Cattle	2.0– 5.0	1.0 – 2.5	0.02 – 0.05
Calves	3.3– 5.6	1.65 – 2.8	0.033 – 0.056
Dogs	2.5 – 25.0	1.25 – 12.5	0.025 – 0.25
Cats	10.0 – 50.0	5.0 – 25.0	0.1 – 0.5

Repeat once daily if necessary.

## 9. ADVICE ON CORRECT ADMINISTRATION

The cap may be safely punctured up to 15 times.



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

Cattle, horses:

Meat and offal: zero days

Milk: zero hours

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Do not store above 25 °C.

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

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 container: 28 days.

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

Special warnings for each target species:

It is recommended to determine the cause(s) of the metabolic or reproductive disorders to define the most appropriate measures of prevention and treatment and the need for a therapy with supplemental phosphorus and vitamin B12.

Special precautions for use in animals:

Due to a deficiency in glucuronidating metabolic pathways in cats, which are involved in benzyl alcohol metabolism, this veterinary medicinal product should be used with caution and the recommended dose should be strictly observed in this species.

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

Benzyl alcohol may cause hypersensitivity (allergic reactions). People with known hypersensitivity to benzyl alcohol should avoid contact with the product.

The product can cause skin, eye or mucous membranes irritation. Dermal, mucous membranes and ocular exposure should therefore be avoided. In case of accidental dermal, mucous membranes or ocular exposure rinse the skin and/or the eye with water.

Do not eat, drink or smoke while handling this product.

Wash hands after use of the veterinary medicinal product.

Pregnancy, lactation or lay:

The safety of the product has not been established in pregnant and lactating cows, mares, bitches and queens. However, its use during pregnancy and lactation in those species should not pose any particular problem.

**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. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

*To be completed in accordance with national requirements after conclusion of the MR phase.*

**15. OTHER INFORMATION**

Package size:

Cardboard box of 1 vial of 100 mL

Cardboard box of 6 carton boxes of 1 vial of 100 mL

Not all pack sizes may be marketed.

*To be completed in accordance with national requirements after conclusion of the MR phase.*

Approved 06 May 2021

