# B. PACKAGE LEAFLET

# PACKAGE LEAFLET

## 1. Name of the veterinary medicinal product

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

## 2. Composition

1 ml contains:

**Active substances:**

| | |
|---|---|
| Butafosfan | 100.00 mg |
| Cyanocobalamin (vitamin $B_{12}$) | 0.05 mg |

**Excipient:**

| | |
|---|---|
| Benzyl alcohol (E 1519) | 20.00 mg |

Clear, pink solution.

## 3. Target species

Cattle
Horses
Dogs

## 4. Indications for use

All target species:
- Supportive treatment and prevention of hypophosphatemia and/or cyanocobalamin (vitamin $B_{12}$) 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 warnings:
None.

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:
This veterinary medicinal product contains benzyl alcohol which may cause hypersensitivity (allergic) reactions. People with known hypersensitivity to benzyl alcohol and other 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 teratogenic, 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, dogs:

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

[1]Has been reported following subcutaneous administration in dogs.
[2]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 using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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

Cattle, 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<br>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 40 times. If more than 40 broachings are required, use of a draw off needle is recommended.
It is recommended to use 100 ml packaging for treatment of dogs.

## 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 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 carton and vial after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days.

## 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

<To be completed nationally.>

Amber glass vial type II closed with bromobutyl rubber stopper and aluminium cap in a cardboard box.

Pack sizes:
Cardboard box with 1 vial filled with 100 ml solution for injection.
Cardboard box with 1 vial filled with 250 ml solution for injection.

Not all pack sizes may be marketed.

## 15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

## 16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release <and contact details to report suspected adverse reactions>:

Veyx-Pharma GmbH
Söhreweg 6
34639 Schwarzenborn
Germany
<Tel: +49 - 5686-9986-0>

Manufacturer responsible for batch release:
Veyx Pharma BV
Forellenweg 16
NL-4941 SJ Raamsdonksveer
The Netherlands

<Local representative and contact details to report suspected adverse reactions:>
<to be completed nationally>