

Vey® Tosal 100 mg/ml + 0.05 mg/ml



Solution for injection for horses, cattle, dogs and cats

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

Veyx-Pharma GmbH
Soehreweg 6
34639 Schwarzenborn
Germany

NAME OF THE VETERINARY MEDICINAL PRODUCT

Vey® Tosal 100 mg/ml + 0.05 mg/ml
Solution for injection for horses, cattle, dogs and cats

STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

1 ml Vey® Tosal 100 mg/ml + 0.05 mg/ml contains:

Active substances:

Butafosfan	100.00 mg
Cyanocobalamin (vitamin B ₁₂)	0.05 mg

Excipient:

Benzyl alcohol (E 1519)	20.00 mg
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INDICATIONS

As supportive treatment of metabolic or reproductive disorders, when supplementation of phosphorous and cyanocobalamin is needed.
In case of peri-parturient metabolic disorders, tetany and paresis (milk fever), the product should be administered in addition to magnesium and calcium, respectively.
Supporting muscle function in the presence of deficiencies of phosphorous and/or cyanocobalamin.

CONTRAINDICATIONS

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

ADVERSE REACTIONS

In cats, following subcutaneous injection in the interscapular region, reactions at injection site (swelling, oedema, erythema and induration) can be observed.

TARGET SPECIES

Cattle, horses, dogs and cats

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

Cattle, horses: for intravenous use
Dogs and cats: for intravenous, intramuscular and subcutaneous use

Animal species/ subcategory	Butafosfan (mg/kg)	Vitamin B ₁₂ (µg/kg)	Product (ml/kg)	Route of administration
Cattle	2.0 - 5.0	1.0 - 2.5	0.02 - 0.05	i.v.
Calves	3.3 - 5.6	1.65 - 2.8	0.033 - 0.056	i.v.
Horses	2.0 - 5.0	1.0 - 2.5	0.02 - 0.05	i.v.
Foals	3.3 - 5.6	1.65 - 2.8	0.033 - 0.056	i.v.
Dogs	2.5 - 25	1.25 - 12.5	0.025 - 0.25	i.v., i.m., s.c.
Cats	10 - 50	5.0 - 25	0.1 - 0.5	i.v., i.m., s.c.

Repeat once daily, if necessary.

ADVICE ON CORRECT ADMINISTRATION

The cap 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 and cats.

WITHDRAWAL PERIODS

<u>Cattle, Horses:</u>	Meat and offal:	zero days
	Milk:	zero hours

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

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

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.

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:

This veterinary medicinal product contains benzyl alcohol which may cause hypersensitivity (allergic) reactions. People with known hypersensitivity to benzyl alcohol should avoid contact with the veterinary medicinal product.

This product may cause irritation of skin, eyes, and mucous membranes. Such contact with the product should be avoided. In case of accidental exposure, rinse the affected area thoroughly with water.

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

Wash hands after use.

Use during pregnancy, lactation or lay::

The safety of the veterinary medicinal 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.

Incompatibilities:

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

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.

To be supplied only on veterinary prescription.

OTHER INFORMATION

Package sizes:

100 ml vial

250 ml vial

