[Version 8.2, 01/2021]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vey Tosal 100 mg/ml + 0.05 mg/ml solution for injection for horses, cattle, dogs and cats (AT/ BE/ BG/ CY/ CZ/ DE/ ES/ FR/ GR/ HR/ HU/ IE/ IT/ LT/ LV/ LU/ MT/ NL/ PL/ PT/ RO/ SI/ SK/ UK))
Veytosal Vet 100 mg/ml + 0.05 mg/ml solution for injection for horses, cattle, dogs and cats (NO/DK/ FI/ IS)
Phoscobal vet 100 mg/ml + 0.05 mg/ml solution for injection for horses, cattle, dogs and cats (SE)
Vey Tosal (EE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substances:

Butafosfan:	100.00 mg
Cyanocobalamin (vitamin B12):	0.05 mg

Excipient:

Benzyl alcohol (E 1519)	20.00 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.
Clear, pink solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, horses, dogs and cats.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

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

4.4 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 B_{12}.

4.5 Special precautions for use

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

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.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 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.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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

Animal species / sub-category	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	IV
Calves	3.3 - 5.6	1.65 - 2.8	0.033 - 0.056	IV
Horses	2.0 - 5.0	1.0 - 2.5	0.02 - 0.05	IV
Foals	3.3 - 5.6	1.65 - 2.8	0.033 - 0.056	IV
Dogs	2.5 - 25	1.25 - 12.5	0.025-0.25	IV, IM, SC
Cats	10 - 50	5.0 - 25	0.1-0.5	IV, IM, SC

Repeat once daily, if necessary.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

None known.

4.11 Withdrawal period(s)

Cattle, horses:
Meat and offal: zero days
Milk: zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: mineral supplements, other mineral products, combinations.
ATCvet code: QA12CX99.

5.1 Pharmacodynamic properties

Butafosfan is an organic phosphorus source for animal metabolism. Among others phosphorus is relevant for energy metabolism. It is essential for gluconeogenesis since most intermediates of that process need to be phosphorylated. Direct pharmacological effects of butafosfan beyond simple phosphorus substitution have additionally been postulated.
Cyanocobalamin is a co-enzyme in the biosynthesis of glucose from propionate. Further it serves as a co-factor to enzymes important in fatty acid synthesis and is important for maintenance of normal haemopoiesis, protection of the liver, and maintenance of muscle tissue, healthy skin, brain and pancreatic metabolism. It belongs to the class of water-soluble B vitamins synthesized by the microbiotic flora in the digestive system of the animals (reticulorumen and large intestine). Owing to the microbes' own requirements, the synthesis usually does not produce sufficient quantities to cover the needs of the entire animal organism. Marked deficiencies occur rarely, even in case of an inadequate supply with cyanocobalamin.

The exact mode of action of cyanocobalamin and butafosfan in combination is not fully understood. Various effects on bovine lipid metabolism of cyanocobalamin and butafosfan in combination have been observed in clinical studies including reduced serum levels of ketosis-related non-esterified fatty acids and β-hydroxybutyric acid.

5.2 Pharmacokinetic particulars

Following intravenous administration to cattle butafosfan is distributed in the extravascular space within minutes and rapidly excreted from the body unchanged. The elimination half-life is 83 to 116 minutes. Within twelve hours after intravenous administration a mean of 74 - 77% of the parent compound is recovered in the urine.
Only traces of butafosfan are found in the milk. Hepatic metabolic degradation was not detected. Butafosfan is rapidly absorbed and eliminated after parenteral administration in all target animal species.

The metabolism of cyanocobalamin is complex and is associated closely with that of folic acid and of ascorbic acid. Vitamin B_{12} is stored in significant amounts in the liver, further storage sites include kidney, heart, spleen and brain. Tissue half-life of vitamin B_{12} is 32 days. In ruminants vitamin B_{12} is excreted primarily in the faeces and in smaller amounts in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E 1519)
Sodium hydroxide (for pH adjustment)
Hydrochloric acid, dilute (for pH adjustment)
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Amber glass vial type II with bromobutyl rubber stopper and aluminium cap with a flip-off seal.

Pack sizes:
Cardboard box with 1 vial of 100 ml
Cardboard box with 1 vial of 250 ml

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Veyx-Pharma GmbH
Soehreweg 6
34639 Schwarzenborn
Germany

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT