SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substances:

Butafosfan	100.00 mg
Cyanocobalamin	0.05 mg

Excipients:

Benzyl alcohol (E1519)	10.00 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection
Clear, reddish to red solution

4. CLINICAL PARTICULARS

4.1 Target species:

Cattle

4.2 Indications for use, specifying the target species

For the supportive treatment of secondary ketosis (e.g in abomasal displacement).

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Not applicable.

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 product.

The product might be mildly irritating to the skin or the eye. Dermal and ocular exposure should therefore be avoided. In case of exposure rinse the skin and/or the eye with water.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy and lactation

No negative effects on the use of the product during pregnancy or lactation have been reported. Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For intravenous use.

Cattle: 5 mg of butafosfan and 2.5 µg of cyanocobalamin per kg bodyweight (bw) corresponding to 5 ml / 100 kg bw daily with a 24 hour interval for three consecutive days.

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

None known.

4.11 Withdrawal periods

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

Alimentary tract and metabolism, mineral supplements, other mineral supplements, other mineral products, butafosfan.
ATCvet code: QA12CX91

5.1 Pharmacodynamic properties

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, 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.
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.

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 nonesterified fatty acids and β-hydroxybutyric acid.

5.2 Pharmacokinetic particulars

Following intravenous administration of a single dose in cattle, the organophosphorus compound butafosfan is distributed in the extravascular space within minutes and rapidly excreted from the body unchanged. The elimination half-life is 83 minutes. Within twelve hours after intravenous administration, 70-90% of the dose are excreted in the urine, 1% is excreted via the faeces. Only traces of butafosfan are found in the milk. Metabolic degradation was not detected. The metabolism of cyanocobalamin is complex and is associated closely with that of folic acid and of ascorbic acid. Vitamin B12 is stored in significant amounts in the liver, further storage sites include kidney, heart spleen and brain. Tissue half-life of vitamin B12 is 32 days. In ruminants vitamin B12 is excreted primarily in the feces and in smaller amounts in the urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Sodium hydroxide (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: 4 years
Shelf life after first opening of 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

100 ml Type II amber glass vial closed with a coated bromobutyl or chlorobutyl rubber stopper and sealed with an aluminium cap.

Carton of 1 x 100 ml, 6 x 100 ml or 12 x 100 ml

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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

Livisto Int'l, S.L.
Av. Universitat Autònoma, 29
08290 Cerdanyola del Vallès (Barcelona)
Spain

8. MARKETING AUTHORISATION NUMBER

Vm 43173/4008

9. DATE OF FIRST AUTHORISATION

15 March 2018

10. DATE OF REVISION OF THE TEXT

July 2022

Approved 27 July 2022