SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butasal-100, 100 mg/ml + 0.05 mg/ml solution for injection for horses, cattle, dogs and cats (EE)
Butasal-100 100 mg/ml + 0.05 mg/ml solution for injection for horses, cattle, dogs and cats (BE, HR, CY, CZ, FR, EL, NL, PT, SK)
Butasal vet 100 mg/ml + 0.05 mg/ml solution for injection for horses, cattle, dogs and cats (DK, FI, IS, SE)
Butasal 100 mg/ml + 0.05 mg/ml solution for injection for horses, cattle, dogs and cats (HU, RO, AT, PL, IE, SI, UK)
Catochem 100 mg/ml + 0.05 mg/ml solution for injection for horses, cattle, dogs and cats (IT, ES, NO)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear red solution without visible particles.

4. CLINICAL PARTICULARS

4.1. Target species

Horses, cattle, 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.

4.3. Contraindications

Do not use in cases of known 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 B12.

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

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.

4.6. Adverse reactions (frequency and seriousness)

None known.

4.7. Use during 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.

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 (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.

The cap may be safely punctured up to 15 times.

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: alimentary tract and metabolism; 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 properties

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 77% of the parent compound is recovered in the urine. Only traces of butafosfan are found in the milk. 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 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 faeces and in smaller amounts in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Benzyl alcohol (E1519)
Sodium citrate
Citric acid

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 of the immediate packaging: 28 days.

6.4. Special precautions for storage

Do not store above 25 °C.
Keep the vial in the outer carton in order to protect from light.

6.5. Nature and composition of immediate packaging

Amber glass vial, closed with a bromobutyl rubber stopper and secured with an aluminium cap or flip-off cap with polypropylene cover.

Package size:
Cardboard boxes of 1 vial of 50 mL or 100 mL
Cardboard box of 6 carton boxes of 1 vial of 50 mL or 100 mL

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

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Vanapere tee 14, Püünsi
Viimsi rural municipality
Harju county 74013
Estonia
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E-mail: info@interchemie.ee

8. MARKETING AUTHORISATION NUMBER(S)

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

9. DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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

10. DATE OF REVISION OF THE TEXT

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

PROHIBITION OF SALE, SUPPLY AND/OR USE

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