1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Calmafusion, 380mg/60mg/50mg, solution for infusion for cattle, sheep and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substances:

Calcium gluconate for injection	380 mg (equivalent to 34.0 mg or 0.85 mmol of Ca^{2+})
Magnesium chloride hexahydrate	60 mg (equivalent to 7.2 mg or 0.30 mmol of Mg^{2+})
Boric acid	50 mg

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for infusion.
Clear, colourless to yellowish brown solution.
pH of the solution 3.0 – 4.0
Osmolality 2040 – 2260 mOsm/kg

4. CLINICAL PARTICULARS

4.1. Target species

Cattle, sheep, pigs.

4.2. Indications for use, specifying the target species

Treatment of acute hypocalcaemia complicated by deficiency of magnesium.

4.3. Contraindications

Do not use in cases of hypercalcaemia and hypermagnesemia.
Do not use in cases of calcinosis in cattle and sheep.
Do not use following administration of high doses of vitamin D_3.
Do not use in cases of chronic kidney insufficiency or in cases of circulatory or cardiac disorders.
Do not use in cattle suffering septicaemic processes in the course of acute mastitis in cattle.
Do not administer inorganic phosphate solutions simultaneously or shortly after the infusion.

4.4. Special warnings for each target species

In case of acute hypomagnesaemia, the administration of a solution with a higher concentration of magnesium may be necessary.

4.5. Special precautions for use

Special precautions for use in animals

The medicinal product must be administered only slowly intravenously.
The solution should be warmed to body temperature before administration.

During the infusion, the heart rate, rhythm and circulation must be monitored. In case of symptoms of overdosing (cardiac arrhythmia, fall in blood pressure, agitation), the infusion should be stopped immediately.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

This veterinary medicinal product contains boric acid, and should not be administered by pregnant women, users of childbearing age, and users trying to conceive.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

This product can cause slight skin and eye-irritation due to the low pH of the product formulation.
Avoid contact with skin and eyes.
Wear protective gloves and glasses.
When the product comes into contact with the skin or eyes, rinse immediately with water.

4.6. Adverse reactions (frequency and seriousness)

Calcium may cause a transient hypercalcaemia with the following symptoms: initial bradycardia, agitation, muscle tremors, salivation, increase in respiratory rate.

Increase in heart rate following initial bradycardia may indicate that overdosing has occurred. In this case the administration should be stopped immediately. Delayed side effects, that can manifest as disorders of general condition, and symptoms of hypercalcaemia 6 – 10 hours after administration are not to be diagnosed as a recurring hypocalcaemia.

4.7. Use during pregnancy, lactation or lay

The safety of the product has not been established during pregnancy and lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.

4.8. Interaction with other medicinal products and other forms of interaction

Calcium increases the effects of heart glycosides.
Calcium amplifies the cardiac effects of β-adrenergic medicinal products and methylxanthines.
Glucocorticoids increase the renal excretion of calcium by way of vitamin D-antagonism.

4.9. Amounts to be administered and administration route

For slow intravenous infusion, recommended over a period of 20 – 30 minutes.
The smaller volumes (less than 50 ml) should be administered by a sterile syringe or syringe infusion pump.

Cattle
Administer 14 – 20 mg Ca^{2+} (0.34 – 0.51 mmol Ca^{2+}) and 2.9 – 4.3 mg Mg^{2+} (0.12 – 0.18 mmol Mg^{2+}) per one kg bodyweight corresponding to 0.4 – 0.6 ml of product per 1 kg bodyweight.

Sheep, calf, pig
Administer 10 – 14 mg Ca^{2+} (0.26 – 0.34 mmol Ca^{2+}) and 2.2 – 2.9 mg Mg^{2+} (0.09 – 0.12 mmol Mg^{2+}) per one kg bodyweight corresponding to 0.3 – 0.4 ml of product per 1 kg bodyweight.

The specified dosages are standard. The dose should always be adapted to the existing deficit and condition of the circulatory system.
The second treatment may be administered not earlier than 12 hours after the first administration. The administration can be repeated twice at 24-hour intervals, if the hypocalcaemic condition is persisting.

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

When the intravenous administration is performed too rapidly, hypercalcaemia and/or hypermagnesemia with cardiotoxic symptoms such as initial bradycardia with subsequent tachycardia, cardiac arrhythmia and in severe cases ventricular fibrillation with cardiac arrest may occur.
Additional symptoms of hypercalcaemia are: motor weakness, muscle tremors, increased excitability, agitation, sweating, polyuria, fall in blood pressure, depression and coma.
Symptoms of hypercalcaemia may persist 6 – 10 hours after the infusion and must not be incorrectly diagnosed as symptoms of hypocalcaemia.

4.11. Withdrawal period(s)

Cattle, pigs, sheep:
Meat and offal: zero days.

Cattle, sheep:
Milk: zero hours.

5. PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Calcium, combinations with vitamin D and/or other drugs
ATCvet code: QA12AX

5.1. Pharmacodynamic properties

The product brings calcium and magnesium to the animal. The parenteral administration increases rapidly the plasmatic concentration of these ions for the treatment of hypocalcemia.

Calcium
Calcium is an essential mineral in the body. Only free ionized calcium in the blood is biologically active and regulates calcium metabolism. Free calcium participates in many functions in the body, e.g. release of hormones and neurotransmitters, impulse transmission, blood coagulation and formation of action potentials in sensitive membranes as well as muscle contraction.

Magnesium
Magnesium, also an essential mineral, is a co-factor in a number of enzymatic processes and transmission mechanisms being important in the formation of impulses and their transmission in nerve and muscle cells. During neuromuscular transmission of motor end plates impulses of magnesium decreases the release of acetylcholine. Magnesium ion can influence the release of transmitters in central nervous system and in vegetative ganglia. Magnesium causes delay of impulse transmission in heart muscle. Magnesium also stimulates the secretion of parathyroid hormone and therefore regulates serum calcium levels.

This veterinary medicinal product contains calcium in an organic compound (as calcium gluconate) and magnesium in form of magnesium chloride as active substances. By the addition of boric acid, calcium borogluconate is formed, which increases its solubility and tissue tolerability.

5.2. Pharmacokinetic particulars

After parenteral administration, calcium and magnesium are rapidly distributed. The rate of protein binding are around 50% for calcium and 30 to 50 % for magnesium. Calcium is mainly excreted via feces and magnesium via kidney.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

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: 3 years.
Shelf life after first opening the container: use immediately.

6.4. Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5. Nature and composition of the immediate packaging

Graduated polypropylene bottle, closed with a bromobutyl rubber stopper and secured with an aluminium cap or flip-off cap with polypropylene cover.
Package size: 500 ml.
Multipack size: 12 x 500 ml in a cardboard box.
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

Interchemie Werken De Adelaar Eesti AS

8. MARKETING AUTHORISATION NUMBER(S)

VPA22812/001/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17/01/2020

10. DATE OF REVISION OF THE TEXT

14/02/2025