

1.NAME OF THE VETERINARY MEDICINAL PRODUCT

Calcibel 240/60/60 mg/ml solution for infusion for horses, cattle, sheep, goats and pigs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Calcium gluconate	240 mg	(equivalent to 21.5 mg calcium)
Magnesium chloride hexahydrate	60 mg	(equivalent to 7.2 mg magnesium)
Boric acid	60 mg	

Excipient(s):

Qualitative composition of excipients and other constituents

Water for injections

Clear, colourless to slightly yellowish solution.

Osmolarity: 1.386 – 1.694 Osmol/l

pH value: 3.2 - 4.0

3. CLINICAL INFORMATION

3.1 Target species

Horses, cattle, sheep, goats, pigs.

3.2 Indications for use for each target species

For the treatment of acute hypocalcaemia.

3.3 Contraindications

Do not use in cases of:

- hypercalcaemia and hypermagnesaemia,
- idiopathic hypocalcaemia in foals,
- calcinosis in cattle and small ruminants,
- septicemia in the course of acute mastitis in cattle,
- chronic renal insufficiency or cases of circulatory or cardiac disorders.

Do not use following application of high doses of vitamin D3 preparations.

Do not use concomitantly or immediately following application of inorganic phosphorous solutions.

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

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for safe use in the target species:

During infusion, the veterinary medicinal product must be administered slowly and at body temperature. During infusion, cardiac rate and rhythm and circulation must be monitored. If any sign of overdose (disturbances of the cardiac rhythm decrease in blood pressure, restlessness) appears, the infusion should be stopped immediately.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Care should be taken to avoid accidental self-injection as this may cause irritation at site of injection. In case of accidental self-injection, seek medical advice immediately and show the label to the physician.

This veterinary medicinal 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 veterinary medicinal product comes into contact with the skin or eyes, rinse immediately with water.

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

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Horse, cattle, sheep, goat, pig

Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	Hypercalcaemia ¹ Bradycardia ² Tachypnoea ² Restlessness ² Muscle tremor ² Increased salivation ² Tachycardia ^{2,3} General illness ^{2,4}
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¹transient

²symptoms of hypercalcaemia

³after an initial bradycardia it may indicate an overdose. In this case, stop the infusion immediately

⁴can occur as a delayed adverse event and with symptoms of hypercalcaemia even 6 - 10 hours after the infusion and must not be misdiagnosed as a recurrence of hypocalcaemia. See also 3.10.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

Pregnancy and lactation:

Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Calcium increases the efficacy of cardiac glycosides.
Calcium increases the cardiac effects of β -adrenergic drugs and methylxanthines.
Glucocorticoids increase the renal excretion of calcium by vitamin D antagonism.

3.9 Administration routes and dosage

Intravenous use.

Cattle:

For slow intravenous infusion over a period of 20-30 minutes.

Adult cattle:

40-50 ml of this veterinary medicinal product per 50 kg body weight
(equivalent to 17.2 – 21.5 mg Ca^{2+} and 5.8 – 7.2 mg Mg^{2+} per kg body weight).

Calf:

30 ml of this veterinary medicinal product per 50 kg body weight
(equivalent to 12.9 mg Ca^{2+} and 4.3 mg Mg^{2+} per kg body weight).

Sheep, goat, pig:

For slow intravenous infusion over a period of 20-30 minutes.

30 ml of this veterinary medicinal product per 50 kg body weight
(equivalent to 12.9 mg Ca^{2+} and 4.3 mg Mg^{2+} per kg body weight).

Horse:

For slow intravenous infusion.

30 ml of this veterinary medicinal product per 50 kg body weight
(equivalent to 12.9 mg Ca^{2+} and 4.3 mg Mg^{2+} per kg body weight).

Infusion in horses should not exceed a rate of 4-8 mg/kg/h calcium (equivalent to 0.18-0.36 ml/kg/h of this veterinary medicinal product). It is recommended to dilute the required dose of this veterinary medicinal product 1:4 with isotonic saline or dextrose and to infuse over at least two hours.

The dosage instructions are given for guidance and must be adapted to the individual deficit and actual circulatory conditions.

After a minimum of 6 hours after treatment, a second treatment may be administered. Additional treatments every 24 hours can be administered if it is clear that on-going symptoms are due to hypocalcaemia.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Overdose and intravenous infusion that is too fast may result in initial bradycardia with subsequent tachycardia, cardiac rhythm disturbances and, in severe cases, ventricular fibrillation' with cardiac arrest.

Additional symptoms of hypercalcaemia are: motor weakness, muscle tremors, increased excitability, agitation, sweating, polyuria, fall in blood pressure, depression and coma.

Exceeding the maximum infusion rate may result in hypersensitivity reactions due to the release of histamine. Symptoms of hypercalcaemia may persist for 6-10 hours after infusion. It is important that these symptoms are not incorrectly diagnosed as a relapse of hypocalcaemia.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Cattle, sheep, goats, horses:

Meat and offal: Zero days.

Milk: Zero hours.

Pigs:

Meat and offal: Zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QA12AX

4.2 Pharmacodynamics

Calcium

Calcium is an essential element that is required for normal nerve and musculoskeletal function, cell membrane and capillary permeability and activation of enzymatic reactions. Only free ionised calcium in the blood is biologically active. Especially in times of increased requirement of calcium, e.g. post-partum, hypocalcaemia may develop.

Magnesium

Magnesium is a cofactor in a number of enzyme systems. It also plays a role in muscular excitement and neurochemical transmission. In the heart magnesium leads to delayed conduction. Magnesium stimulates the secretion of parathyroid hormone and therefore regulates serum calcium levels. In ruminants, especially after intake of young, protein-rich grass, hypomagnesaemia may develop.

The veterinary medicinal product contains calcium in an organic compound 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. The main indication for its use is hypocalcaemic conditions. The addition of magnesium antagonises possible cardiac effects of calcium, especially following overdose or rapid infusion, and helps correct hypomagnesaemia, which frequently occurs in combination with hypocalcaemia.

4.3 Pharmacokinetics

Calcium

More than 90% of total body calcium is found in bone. Only about 1% is free to be exchanged with the calcium in serum and interstitial fluid. In the serum, 35 – 40% of calcium is bound to proteins, 5 – 10% is complexed with anions and 40 – 60% is in the ionized form. Calcium is eliminated mainly through the faeces with small amounts eliminated in the urine.

Magnesium

In adult animals, around 50% of magnesium is found in bone, 45% in the intracellular space and 1% in the extracellular space, of which 30% is bound to proteins and the remainder exists as free ions. The amount of magnesium utilized from the nutrition varies between 15 and 26 % in adult cattle. Approximately 80% is absorbed through the rumen. When grazing on young protein-rich grass pasture, the absorption may decrease to 8%. Magnesium is excreted by the kidneys at a rate proportional to the serum concentration and glomerular filtration.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:	3 years.
Shelf life after first opening the immediate packaging:	use immediately.

5.3 Special precautions for storage

Do not refrigerate or freeze.

5.4 Nature and composition of immediate packaging

Bottle for infusion made of polypropylene with scaling, closures made of bromobutyl rubber stopper, aluminium caps with tear-off.

Pack sizes:

1 x 500 ml
6 x 500 ml
12 x 500 ml

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bela-Pharm GmbH & Co. KG

7. MARKETING AUTHORISATION NUMBER(S)

VPA10445/003/001

8. DATE OF FIRST AUTHORISATION

22/04/2016

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

07/04/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).