C-B-Gluconat 38% plus 6%

Solution for infusion for slow intravenous administration

for horses, cattle, sheep, goats, pigs

100 ml solution for infusion contains:

Active substances:

Calcium gluconate monohydrate 38.0 g
(equivalent to Ca^{2+}: 3.4 g or 85 mmol)
Magnesium chloride hexahydrate 6.0 g
(equivalent to Mg^{2+}: 0.72 g or 30 mmol)
Boric acid 5.0 g

Excipients:

Water for injection purposes

Clear, slightly yellowish-brown solution for infusion.
Osmolarity: 0.690 - 0.850 osmol/l
pH value: 3.0 - 4.0

Available on prescription only

MAH-No.: 6933051.00.00

Target species

Horse, cattle, sheep, goat, pig.

Indications for use

Acute hypocalcaemic conditions.
Supportive therapy in allergy, anaphylaxis, haemorrhagic diathesis.

Contraindications

Do not use
- for hypercalcaemia and hypermagnesaemia
- for idiopathic hypocalcaemia in foals
- for calcinosis in cattle and small ruminants
- for septicaemic processes in the course of acute mastitis in cattle
- following high-dose administration of Vit D_3 preparations
- for chronic renal insufficiency
- concomitant or immediately following intravenous administration of inorganic phosphate solutions.

Special warnings

Special precautions for safe use in the target species:
Intravenous administration must be slow.
The heart and circulation must be monitored during the infusion. If symptoms of an overdose occur (in particular cardiac arrhythmia, drop in blood pressure, restlessness), the infusion should be stopped immediately.

Pregnancy and lactation:
No details.

Interactions with other medicinal products and other interactions:
Calcium increases the effectiveness of cardiac glycosides.

Calcium increases the cardiac effects of β-adrenergics and methylxanthines.
Glucocorticoids increase the renal excretion of calcium through vitamin D antagonism.
Mixing with other medicinal products should be avoided due to possible incompatibilities.

Overdose:
If the intravenous infusion is administered too quickly or overdosed, the calcium content can lead to hypercalcaemia and/or hypermagnesaemia with cardiotoxic symptoms such as initial bradycardia with subsequent tachycardia, cardiac arrhythmia and, in severe cases, ventricular fibrillation with cardiac arrest. Other hypercalcaemic symptoms to be noted are: motor weakness, muscle tremors, increased excitability, restlessness, sweating, polyuria, drop in blood pressure, depression and coma.
If the maximum infusion rate is exceeded, allergic symptoms may occur due to the release of histamine. In such cases, the infusion should be stopped immediately.
Symptoms of hypercalcaemia can still occur 6-10 hours after the infusion and must not be misdiagnosed as a recurrence of hypocalcaemia due to the similarity of the symptoms.

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

Adverse events
Target species: Horse, cattle, sheep, goat, pig

Indeterminate frequency (cannot be estimated on the basis of the available data):	Hypercalcaemia [1] Increase in heart rate [2] Increase in respiratory rate Restlessness Muscle tremors Salivation Disturbance of the general condition [3]

[1] transient
[2] after an initial bradycardia should be interpreted as a sign of an incipient overdose. In this case, the infusion should be cancelled.
[3] May occur as a delayed side effect and with symptoms of hypercalcaemia even 6-10 hours after the infusion and must not be misdiagnosed as a recurrence of hypocalcaemia. See also section „Overdose".

If you notice any side effects, even those not already listed in the package leaflet, or you think that medicine product has not worked, please contact in the first instance, your veterinarian.

Dosage for each species, routes and method of administration
For slow intravenous application.

· Bovine
acute hypocalcaemic conditions:
20-30 ml of the veterinary medicinal product per 50 kg body weight
(equivalent to 0.34-0.51 mmol Ca^{2+} and 0.12-0.18 mmol Mg^{2+} per kg body weight)

Supportive therapy for allergies, anaphylaxis, haemorrhagic diathesis:
15-20 ml of the veterinary medicinal product per 50 kg body weight
(equivalent to 0.26-0.34 mmol Ca^{2+} and 0.09-0.12 mmol Mg^{2+} per kg body weight)

· Horse, calf, sheep, goat, pig
30 ml of the veterinary medicinal product per 50 kg body weight
(equivalent to 0.26-0.34 mmol Ca^{2+} and 0.09-0.12 mmol Mg^{2+} per kg body weight)

The intravenous infusion must be administered slowly over a period of 20-30 minutes.
The dosage details are guidelines and should always be adapted to the existing deficit and the respective circulatory condition.
The first follow-up treatment may be given after 6 hours at the earliest. Further follow-up treatments at 24-hour intervals if it is certain that the persistence of symptoms is due to a continuing hypocalcaemic state.

Advice on correct administration
See section „Dosage for each species, routes and method of administration".

Withdrawal periods

Cattle, sheep, goat, horse:	Edible tissues: Zero days, Milk: Zero hours
Pig:	Edible tissues: Zero days

Special storage precautions
Keep out of the sight and reach of children.
Do not store below 8 °C.
Only use clear solutions in undamaged containers.
Shelf life after first opening the immediate packaging: use immediately.
Any residues remaining in the container must be discarded.

Special precautions for disposal
Unused veterinary medicinal products should preferably be disposed of at hazardous waste collection centres. If disposed of together with household waste, it must be ensured that this waste cannot be misused. Veterinary medicinal products must not be disposed of with waste water or via the sewage system. These measures serve to protect the environment. Ask your veterinarian or pharmacist how to dispose of medicines that are no longer needed.

Classification of veterinary medicinal products
Veterinary medicinal product subject to prescription.

Marketing authorisation numbers and pack sizes
6933051.00.00

Pack sizes
Infusion bottle made of polypropylene, sealed with a bromobutyl rubber stopper and aluminium cap. 6 x 500 ml and 12 x 500 ml infusion bottles in a carton.

Pack sizes Original packaging:
1 infusion bottle with 500 ml infusion solution.
Carton containing 6 infusion bottles with 500 ml infusion solution each.
Carton containing 12 infusion bottles with 500 ml infusion solution each.

Pack sizes Bundle pack:
Carton containing 6 infusion bottles with 500 ml infusion solution each.
Carton containing 12 infusion bottles with 500 ml infusion solution each.

Not all pack sizes may be marketed.

Date on which the package leaflet was last revised
23.04.2024

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