C-B-Gluconat 38% plus 6%

Solution for slow intravenous infusion

Target species: Horses, cattle, sheep, goats and pigs

Name and address of the marketing authorisation holder:
bela-pharm GmbH & Co. KG, Lohner Str. 19, 49377 Vechta - Germany

Statement of the active substance(s) and other ingredient(s):
100 ml solution for infusion contain:
Pharmacological active substance:

Calcium gluconate	38.0 g
(corresponding to Ca^{2+}: 3.4 g resp. 85 mmol)	
Magnesium chloride, 6 H2O	6.0 g
(corresponding to Mg^{2+}: 0.72 g resp. 30 mmol)	
Boric acid	5.0 g

Clear, slightly yellowish-brown solution for infusion.
The solution for infusion is free from endotoxins.
Strong hypertonic solution.

Indications:
Horse, cattle, sheep, goat, pig: Acute hypocalcaemic conditions.
Supportive therapy in allergy, anaphylaxis, haemorrhagic diathesis.

Contraindications:
- hypercalcaemia and hypermagnesaemia,
- idiopathic hypocalcaemia in *foals*,
- calcinosis in cattle and small ruminants,
- septicaemic processes in the course of acute mastitis in *cattle*,
- application after high doses of vitamin D_3 preparations,
- chronic renal insufficiency,
- concomitant or immediately following application of inorganic phosphorous solutions.

Adverse reactions (frequency and seriousness):
Even when given in therapeutic dosage, the content of calcium may provoke a transient hypercalcaemia with the following symptoms:
- initial bradycardia,
- restlessness, muscle tremblement, salivation,
- increase in respiratory rate.

An increase of heart rate following an initial bradycardia is to be judged as start of an overdosage. If this is the case, stop the infusion immediately. Delayed undesirable effects may appear in form of disturbances of the general state of health and symptoms of hypercalcaemia up to 6 – 10 hours after administration and must not be diagnosed as a relapse of hypocalcaemia.
See also “Overdose”.

Target species:
Horse, cattle, sheep, goat, pig.

Dosage for each species, route(s) and method of administration:
For slow intravenous infusion.

Cattle:
acute hypocalcaemic conditions:
20-30 ml C-B-Gluconat 38% plus 6% per 50 kg body weight
(corresponding to 0.34 – 0.51 mmol Ca^{2+} and 0.12 – 0.18 mmol Mg^{2+} per kg b.w.).

Supportive therapy in allergy, anaphylaxis, haemorrhagic diathesis:
15-20 ml C-B-Gluconat 38% plus 6% per 50 kg body weight
(corresponding to 0.26-0.34 mmol Ca^{2+} and 0.09 - 012 mmol Mg^{2+} per kg b.w.).

Horse, calf, sheep, goat, pig:
15-20 ml C-B-Gluconat 38% plus 6% per 50 kg body weight
(corresponding to 0.26 – 0.34 mmol Ca^{2+} and 0.09 – 0.12 mmol Mg^{2+} per kg b.w.).

The intravenous infusion must be executed slowly in a period of 20-30 minutes.
The dosage instructions are given for guidance and must be adapted to the individual deficit and actual circulatory conditions.
A first repeated administration can be done at the earliest 6 hours following the initial application. Additional infusions in intervals of 24 hours, if it is ensured, that the continuation of symptoms is caused by the lasting of the hypocalcaemic conditions.

Advice on correct administration:
Special warnings for each target species:
Not known.
Special precautions for use in animals:
Intravenous application must be executed slowly.
During infusion, cardiac rate and rhythm and circulation must be controlled. If any sign of overdosage (disturbances of the cardiac rhythm, decrease in blood pressure, restlessness) appears, the infusion has to be stopped immediately.
Special safety precautions to be taken by the person administering the medicinal product to animals:
Not known.
Use during pregnancy, lactation or lay:
No comments.
Interaction with other medicinal products and other forms of interaction:
Calcium increases the efficacy of cardiac glycosides.
Calcium increases the cardiac effects of βadrenergic drugs and methylxanthines.
Glucocorticoids increase the renal excretion of calcium by vitamin D antagonism.
Avoid mixtures with other medicinal products as incompatibilities may be possible.
Overdose (symptoms, emergency procedures, antidotes):
When the intravenous infusion is executed to fast or in overdosage, on the basis of its contents of calcium, hypercalcaemia or hypermagnesaemia with cardiotoxic symptoms as initial bradycardia with subsequent tachycardia, disturbances of the cardiac rhythm, and in severe cases ventricular fibrillation may occur. Other symptoms of hypercalcaemia are: motoric weakness, muscle tremblement, increased excitability, restlessness, sweetening, polyuria, decrease in blood pressure, depression and coma.

Exceeding of the maximal infusion rate may provoke allergic reactions due to the release of histamin.
In these cases, the infusion must be stopped immediately.
Symptoms of hypercalcaemia may still occur after 6 – 10 hours following infusion and shall not be diagnozed based on the similarity of symptoms as a relapse of hypocalcaemia.
Incompatibilities:
Avoid mixtures with other medicinal products as incompatibilities may be possible.

Withdrawal period(s):

Cattle, sheep, goat, horse:	edible tissues:	1 day
	Milk:	1 day
Pig:	edible tissues:	1 day

Special storage precautions:
Do not store at temperatures below 8 °C.
Keep out of reach and sight of children.
Use only clear solutions in original unopened packings.
Do not use after the expiration date stated on the label.

Special warnings:
None.

Special precautions for the disposal of unused product or waste materials:
Remaining quantities shall be preferably given to pollutant collecting points. When wasted together with the general household waste, it has to be ensured that no misuse of the pharmaceutical is possible. Veterinary pharmaceuticals must not be wasted with waste water or sewage systems. Local regulations for the disposal of pharmaceuticals have to be observed.

Date on which the package leaflet was last approved: 11.08.2011

Marketing authorisation number: 6933051.00.00 (Germany)

For Veterinary use only.

Available on prescription only!