Calciveyxol® 38

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Infusion solution with calcium gluconate, boric acid and magnesium chloride

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT
Veyx-Pharma GmbH
Soehreweg 6
34639 Schwarzenborn
Germany

NAME OF THE VETERINARY MEDICINAL PRODUCT
Calciveyxol® 38
Solution for infusion for slow intravenous use for cattle, pigs and sheep
Strongly hypertonic solution

STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS
1 ml contains:

Active substances:

380.00 mg	calcium gluconate (Ph. Eur) (corresponding to Ca^{2+}: 34.0 mg or 0.85 mmol, respectively)
60.00 mg	magnesium chloride hexahydrate (corresponding to Mg^{2+}: 7.2 mg or 0.30 mmol, respectively)
50.00 mg	boric acid

Excipients:
Water for injections

INDICATIONS
Acute hypocalcaemic conditions.
As a supporting therapy for allergies, urticaria, haemorrhagic diathesis, uterine inertia.

CONTRAINDICATIONS
- Hypercalcaemia and hypermagnesaemia
- Calcinosis in cattle and sheep
- Use following high dosages of vitamin D_3 preparations
- Chronic kidney insufficiency
- Simultaneous or shortly following intravenous application of inorganic phosphate solutions

ADVERSE REACTIONS
Even when the therapeutic dosage is administered, a transient hypercalcaemia can develop due to the calcium content. This condition manifests itself as follows:

- initial bradycardia
- agitation, muscular tremors, salivation
- increased respiratory rate

The increase in the heart rate following initial bradycardia is to be taken as the sign of a beginning overdosage. In this case the infusion must be stopped. Delayed side effects may occur in the form of disorders of the general condition and with symptoms of a hypercalcaemia even 6 - 10 hours after the infusion. They should not be incorrectly diagnosed as a recurrent hypocalcaemia.
See also “Overdose” under Special warnings.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon or pharmacist.

TARGET SPECIES
Cattle, pigs, sheep

DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION
For slow intravenous application.

Cattle:
Acute hypocalcaemic conditions:
20 - 30 ml Calciveyxol® 38 per 50 kg BW, intravenously
(equivalent to 0.34 - 0.51 mmol Ca^{2+} and 0.12 - 0.18 mmol Mg^{2+} per kg BW)

Supportive therapy for allergies, urticaria, haemorrhagic diathesis, uterine atony:
15 - 20 ml Calciveyxol® 38 per 50 kg BW, intravenously
(equivalent to 0.26 – 0.34 mmol Ca^{2+} and 0.09 - 0.12 mmol Mg^{2+} per kg BW)

Sheep, calf, pig:
3 - 4 ml Calciveyxol® 38 per 10 kg BW, intravenously
(equivalent to 0.26 - 0.34 mmol Ca^{2+} and 0.09 - 0.12 mmol Mg^{2+} per kg BW)

BW = body weight

The intravenous infusion must be given slowly over a period of 20 - 30 minutes. The specified dosages are standard values. They should always be adapted to the existing deficit and the particular condition of the circulatory system.
The first repeat treatment must not be carried out earlier than 6 hours after the initial treatment. Additional repeat treatments can be given at intervals of 24 hours, when it is assured that the persisting symptoms relate to a maintained hypocalcaemic condition.

ADVICE ON CORRECT ADMINISTRATION
See “Special warnings”

WITHDRAWAL PERIODS

Cattle, sheep:	Meat and offal	Zero days
	Milk	Zero days
Pigs:	Meat and offal	Zero days

SPECIAL STORAGE PRECAUTIONS
Keep out of the reach and sight of children.

Do not refrigerate or freeze. Protect from frost.
Consume content immediately. Dispose of residual content of the container.
Use only clear solutions from intact containers.

Do not use after the expiry date which is stated on the label and the outer carton.

SPECIAL WARNING(S)
Special precautions for use:
Special precautions for use in animals:
The intravenous application must be carried out slowly. During the infusion, the heart and circulation must be continuously monitored. In case of symptoms of overdosing (especially cardiac arrhythmia, fall in blood pressure, agitation), the infusion should be stopped immediately.

Interaction with other medicinal products and other forms of interaction:
Calcium increases the efficacy of heart glycosides. The cardiac effects of ß-adrenergics and methylxanthines are amplified by calcium. Glucocorticoids increase the renal excretion of calcium by way of vitamin D-antagonism. Mixing with other medicinal products is to be avoided because of possible incompatibilities.

Overdose (symptoms, emergency procedures, antidotes), if necessary:
A too rapid rate of intravenous infusion or overdosing can lead to a hypercalcaemia (and/or hypermagnesaemia) with cardiotoxic symptoms such as tachycardia following initial bradycardia, cardiac arrhythmia and in severe cases ventricular cardiac fibrillation with cardiac arrest.
The following are to be observed as additional hypercalcaemic symptoms: motor weakness, muscular tremor, increased excitability, agitation, sweating, polyuria, drop in blood pressure, depression as well as coma. In these instances the infusion should be stopped immediately. Symptoms of a hypercalcaemia can also occur 6 - 10 hours after the infusion and must not be incorrectly diagnosed as recurrent hypocalcaemia due to the similarity of the symptoms.

Incompatibilities:
Mixing with other medicinal products is to be avoided because of possible incompatibilities.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY
Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Ask your veterinary surgeon how to dispose of medicines no longer required.

To be supplied only on veterinary prescription.

OTHER INFORMATION
Package size:
500 ml bottle