

Efficacy and safety of Catosal® in the treatment of parturient paresis in cows

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Objective:

To evaluate the efficacy and safety of Catosal® (synonym Coforta®) as a supportive treatment of parturient paresis in cows according to Good Clinical Practice (VICH GL9) standards.

Design:

Confirmatory, multi-centre, controlled, masked, randomised parallel group study.

Animals:

Adult cows with typical clinical signs of milk fever and a positive reaction to specific electrolyte infusion by rising. In total, 37 animals were enrolled into the study. Out of these, 29 patients were included in the “per protocol” population (Catosal®: n=15; NaCl: n=14) which was used for analysis of efficacy.

Study groups:

Catosal® (Bayer) or physiological saline (NaCl), administered intravenously as a single dose of 5 ml/kg body weight.

Schedule of events:

Upon enrolment animals were allocated to one of the two study groups, animal details and farm history were recorded, and a clinical examination was performed. Baseline blood samples were collected before administration of a specific electrolyte infusion with commercially available products. During the 24 hours following treatment, the animals were repeatedly observed for any recurrence of milk fever or other symptoms. An additional blood sample was collected at the final examination 24 hours after treatment (or earlier if relapse occurred).

Results:

The primary efficacy criterion was the change in blood levels of calcium, observed 24 hours post treatment. This change, considered to be equivalent to the clinical success rate, was considerably higher in the Catosal® group than in the control group. The difference just failed to achieve the level of statistical significance ($p=0.0958$), but was clinically relevant in terms of the risk of relapse as the mean calcium level achieved in the Catosal® group exceeded the critical level for the acute risk of relapse (1.5 mmol/l).

No changes were observed with regard to serum levels of phosphorus or magnesium.

There were no cases of clinical ketosis during the study. Serum values of non-esterified fatty acids and β -hydroxybutyrate were shown to be slightly elevated in both treatment groups.

No treatment-related adverse events were observed.

Conclusion:

Based on the better stabilisation of serum calcium levels by Catosal® relative to saline administration, as well as the excellent tolerability observed, the results of the present study support the clinical efficacy and safety of Catosal® as an adjunct treatment of electrolyte therapy of parturient paresis in cattle.

Clinical and metabolic effects of Catosal[®] in cows with abomasal displacement

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Objective:

Abomasal displacement is accompanied by symptoms of indigestion, including disturbances of the abomasal emptying rate, and metabolic disorders.

The aim of this study was to investigate the clinical and metabolic effects of Catosal[®] (synonym Coforta[®]) in cows with left abomasal displacement.

Experimental design:

Upon inclusion, the animals were allocated alternately to the test groups. Animals with severe systemic disorders were not included in the study. Fifteen cows received 25 ml of Catosal[®] as an intravenous bolus about 2 hours before the start of surgery. The other 15 cows served as an untreated control group. Both groups received the same co-medication consisting of an i.v. 5% glucose-containing saline solution (20 l/24 h), twice-daily antibiotic treatment, flunixin meglumine, and propylene glycol. The abomasal emptying rate was measured using a xylose absorption test (50% D-xylose, 500 mg/kg BW). Two hours after premedication, the abomasum was repositioned surgically.

The following parameters were assessed at the start of study and at predefined intervals for up to 72 hours post surgery: feed intake, rumination, rumen movements, rectal body temperature, pulse and respiration rates, D-xylose blood levels, blood pH, base excess, hydrogen carbonate levels in blood and pCO₂, haematocrit, haemoglobin, haemogram, serum electrolytes, ASAT, GLDH, CK, protein, glucose, cholesterol, urea, bilirubin, β-hydroxybutyrate, free fatty acids, haptoglobin, antioxidative status and serum cortisol levels.

Results:

Feed intake, rumen movements and rumination returned to physiological values significantly earlier in the Catosal[®] group ($p < 0.05$). The clinical findings were supported by beneficial effects on β-hydroxybutyrate, free fatty acids, ASAT and creatine kinase levels in the blood (all $p < 0.05$). The abomasal emptying rate was faster in cows given Catosal[®] than in the control group.

There was also a tendency towards Catosal[®]-related improvements in other parameters (glucose, bilirubin, GLDH), pulse and respiration rate, although these differences could not be confirmed statistically. The anti-oxidative status, serum cortisol levels and haematological parameters were not affected by treatment.

Conclusion:

Catosal[®] mediates stabilisation of clinical and relevant metabolic parameters during convalescence from abomasal displacement.



Efficacy and safety of Catosal® in the concomitant treatment of ketosis in cows with left abomasal displacement

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Objective:

To evaluate the efficacy and safety of Catosal® in the treatment of ketosis in cows with left abomasal displacement according to Good Clinical Practice (VICH GL9) standards.

Design:

Multi-centre, controlled, randomised and blinded field study.

Animals:

Cows with left abomasal displacement and confirmed ketosis. In total, 140 patients were included in the assessment of safety and efficacy (“intent to treat” population, Catosal®: n=70; control: n=70). Out of these, 120 patients were included in the “per protocol” population (Catosal®: n=60; control: n=60) which was used for analysis of efficacy.

Treatment groups:

Catosal® or the control product (physiological saline, NaCl), administered intravenously for 3 consecutive days at a dose volume of 5 ml/100 kg body weight.

Schedule of events:

On study day 0, animal details and farm history were recorded, and a general physical and clinical examination was performed. Blood samples for baseline values were taken before treatment with Catosal® or the control product and before surgery for reposition of the left abomasum was performed. The cows were randomised to one of the two treatment groups and treatment was administered. Clinical re-examinations were performed and additional blood samples were taken at several time-points between surgery and the final examination on day 3.

Results:

The primary efficacy criterion was the proportion of healthy animals, defined as ≥ 3 rumen movements/3 minutes. Superiority was tested using a logistic regression for days 1 to 3 after onset. On day 2, 39 Catosal®-treated patients and 29 control patients were healthy ($p=0.0381$). On day 3, 49 patients treated with Catosal® and 38 animals treated with NaCl were healthy ($p=0.0126$). Secondary clinical efficacy parameters confirmed that rumen activity was in a normal range earlier with Catosal® compared to the control group, which again was statistically significant ($p=0.0167$). No group differences were observed for hay and concentrate consumption or presence of rumination. The analysis of betahydroxybutyrate just failed to confirm superiority for the Catosal® group ($p=0.0592$). There was no difference between the two treatment groups for bilirubin, cortisol, creatine kinase, glutamate dehydrogenase and free fatty acids. No treatment-related adverse events were observed.

Conclusion:

This study confirmed the efficacy and safety of Catosal® in the treatment of ketosis in cows with left abomasal displacement.