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.