

Efficacy and Safety of Catosal® 10% in the concomitant treatment of ketosis in cows with left abomasal displacement

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SUMMARY

The objective of the study was the assessment of the clinical efficacy and safety of Catosal® 10% in the treatment of ketosis in cows with left abomasal displacement. Cows with left abomasal displacement and confirmed ketosis were enrolled in 4 veterinary clinics. If the patients were found suitable for enrolment on day 0, animal details and farm history were recorded, and a general physical and clinical examination was performed. Blood samples for the baseline values were taken before treatment with the investigational or control product and before surgery for reposition of the left abomasum was performed. The cows were allocated to one of the treatment groups according to the randomisation list. Treatment was administered intravenously by the dispenser for 3 days. Patients were clinically re-examined on day 0 hours 6 and 10, day 1, day 2 and day 3. Blood samples were taken day 0 hours 0, 2, 4, 6, 10, day 1, day 2 and day 3.

This report had to be prepared after the completion of 53 and 54 animals to the Catosal 10% and the negative control group respectively as of regulatory purposes. It was planned to have at least 64 completers per group. Further investigations will be done in order to finally complete this study. However, the current results are presented.

The total of 107 cows treated with either the investigational veterinary product (n=53) or with the control product (n=54) were included in the assessment of safety and efficacy ("intention to treat" population). Ninety-one patients were included in the "per-protocol" population (Catosal® 10%: n=45; control: n=46) which was also used for analysis of efficacy.

The primary efficacy criterion was the proportion of healthy animals (defined as ≥ 3 rumen movements/ 3 minutes) on day 3. Superiority was tested using a logistic regression at 3 days after onset. Thirty seven of 45 patients treated with investigational veterinary product and 31 of 46 animals were healthy at day 3. The difference just missed the level of statistical significance ($p=0.0536$). Secondary clinical efficacy parameters confirmed for Catosal® 10% that rumen activity was earlier in a normal range compared to the control group which again was statistically just not significant ($p=0.0542$). No group differences for hay and concentrate consumption and presence of rumination were observed. The analysis of β -hydroxybutyrate (BHB) confirmed superiority for the Catosal® 10% group ($p=0.0500$). There was no difference between the two treatment groups for bilirubin, cortisol, creatinkinase, GLDH and free fatty acids.

Based on the clinical parameters and the BHB values, Catosal® 10% is regarded as efficacious and safe as a concomitant treatment in ketotic cows with left abomasal displacement compared to a negative control group.