

Final Report on Field Safety Evaluation of Titanium[®] 5 L5

Elanco Study No. TR-03

Elanco

Titanium

Study overview

The safety of Titanium 5 L5 livestock vaccine administered intramuscularly (IM) and subcutaneously (SQ) was evaluated in weaned, non-pregnant cattle under field conditions at three locations.

Key study results

Titanium 5 L5 was demonstrated to be safe for use in weaned, non-pregnant cattle under field conditions when administered SQ or IM.

Background information

TRIAL DESIGN

- Study performed by three investigators on five herds of weaned, non-pregnant cattle at locations in three states (Texas, South Dakota, Nebraska)
- Test subjects received either the vaccine or a placebo
- All animals were observed for onset of adverse reactions for 14 days following vaccination

MATERIALS AND METHODS

- Vaccine contained:
 - Modified-live virus (MLV) infectious bovine rhinotracheitis
 - MLV bovine viral diarrhea virus, types 1 and 2
 - MLV parainfluenza₃
 - MLV bovine respiratory syncytial virus
 - Killed *Leptospira canicola*, *L. grippotyphosa*, *L. hardjo*, *L. icterphaemorrhagiae* and *L. pomona*
- 896 total hd in the study
 - 746 hd received 2.0 mL doses — 390 hd IM; 356 hd SQ
 - 150 hd received 2.0 mL placebo doses — 75 hd IM; 75 hd SQ
- Injection sites were observed daily for 14 days post-vaccination for reactions, including:
 - Injection-site swelling or abscesses
 - Systemic reactions, such as lameness, anorexia, depression

Study results

Table 1. Summary of treatments and outcomes by test site

Study site	Cattle treated, No.				Trial outcomes (reactions)
	Vaccine		Control		
	IM	SQ	IM	SQ	
South Dakota	125	125	25	25	No reactions observed
Texas	125	125	25	25	No reactions observed
Nebraska	0	72	0	0	No reactions observed
	0	34	0	25	
	140	0	25	0	
Overall field trial summary	390	356	75	75	No reactions observed

Key findings

- No local or systemic reactions were observed in any of the cattle receiving vaccine or placebo during the 14-day post-vaccinal observation period
- Titanium 5 L5 was demonstrated to be safe for use in weaned, non-pregnant animals under field conditions when administered IM or SQ

The label contains complete use information, including cautions and warnings. Always read, understand and follow the label and use directions.

Do not vaccinate within 21 days of slaughter.