Librela™ (bedinvetmab injection)

Results of a Comparator Clinical Trial Evaluating the **Efficacy** and **Safety** of Librela vs Meloxicam[1]

Innes et al: A randomised, parallel group clinical trial comparing bedinvetmab to meloxicam for the management of canine osteoarthritis. European Society of Veterinary Orthopaedics and Traumatology Meeting Proceedings, 2024, Lisbon, Portugal.

Study Objectives[1]

- Compare efficacy
- Compare safety

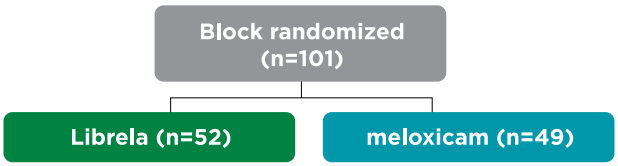
Study Benefits and Limitations[1]

- First study to do a direct comparison of Librela vs an NSAID
- Clinical considerations for veterinarians should be based on the product labels
- Study was not blinded; dogs were block randomized into either the Librela or meloxicam group

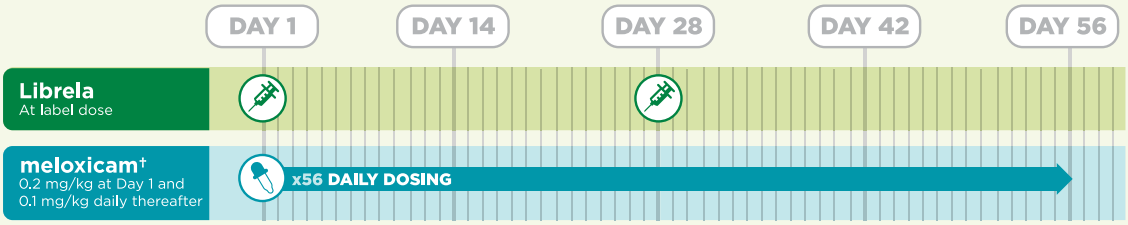
Study Design and Methods[1]

Prospective, multicenter, open-label randomized clinical trial

Study design was established following both a literature review and based on statistical sampling estimates needed to show a clinically meaningful difference using the Canine Orthopedic Index (COI).



Visit Days* and Treatment



*COI and VCA at each visit.

†Dog owners were required to be compliant with meloxicam dosing throughout the study. Weight of the meloxicam was measured at each follow-up visit.

VCA=Veterinary Categorical Assessment.

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Study Results*

In this clinical study, Librela and meloxicam showed significant reductions in OA pain, which improved over time[1]

These results provide additional information on the efficacy and safety of Librela, along with comparative data, providing veterinarians with additional insights when selecting treatment options for dogs with OA pain.

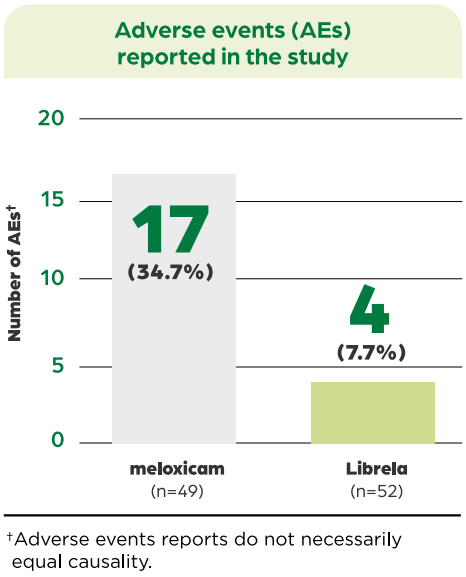
Effective pain management[1]

The primary end point for efficacy was change from baseline COI score.

- Equivalent efficacy to meloxicam at all timepoints measured
- Greater numerical improvement than meloxicam from baseline over time (although the difference was not statistically significant)

In this study, Librela was associated with fewer adverse events than meloxicam[1]

- The Librela-treated group had 4 events vs 17 in the meloxicam group (9/17 were GI system disorders)
- The following page has information pertaining to the labels for Librela and meloxicam



†Adverse events reports do not necessarily equal causality.

*Data analysis was performed using R (version 4.2, R Foundation for Statistical Computing) and MLwiN (version 3.10, Centre for Multilevel Modelling, University of Bristol) on a 'per protocol' and 'intent to treat' basis. For intent to treat analysis missing data were imputed using multiple imputations by chained equations with the R package mice. The COI data were analyzed separately using a general linear mixed effects model for repeated measures with the change in COI from baseline as the outcome. The initial COI score used a covariate, with random effects of site and dog (for repeated measures) and fixed effects of treatment and visit. Adverse events and any binary data were analyzed using generalized linear mixed effect models with binomial distribution and logit link. The model included fixed effect of treatment and visit and random effects of site and dog.

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Product Labeling: Veterinarians should rely on product labels when making clinical decisions

Librela product label link

US field study adverse events[2]

Adverse events*	Librela (n=135)	Saline Placebo (n=137)
Urinary tract infection	11%	8%
Bacteria skin infection	8%	7%
Dermatitis	7%	6%
Dermal mass	6%	4%
Erythema	4%	4%
Dermal cyst(s)	3%	2%
Pain on injection	3%	2%
Inappropriate urination event	3%	1%
Histiocytoma	2%	0%

*An adverse event may have occurred more than once in a dog; only the first occurrence was counted.
†For the vast majority of dogs, an increase in blood urea nitrogen (BUN) was not associated with clinical signs or changes in other renal parameters.

EU field study adverse events[2]

Adverse events*	Librela (n=138)	Saline Placebo (n=137)
Increased blood urea nitrogen†	14%	5%
Lethargy	4%	0%
Emesis	3%	1%
Anorexia	2%	0%
Lameness	2%	1%
Cough	2%	1%

meloxicam product label link

Adverse events observed during two field studies[3]

Clinical observation	meloxicam (n=157)	Placebo (n=149)
Vomiting	40	23
Diarrhea/soft stool	19	11
Bloody stool	1	0
Inappetence	5	1
Bleeding gums after dental procedure	1	0
Lethargy/swollen carpus	1	0
Epiphora	1	0

Adverse Events: Field safety was evaluated in 306 dogs. Based on the results of two studies, GI abnormalities (vomiting, soft stools, diarrhea, and inappetence) were the most common adverse reactions associated with the administration of meloxicam. The table opposite lists adverse reactions and the numbers of dogs that experienced them during the studies. Dogs may have experienced more than one episode of the adverse reaction during the study.[3]

Previous studies have reported the efficacy of meloxicam and also reported a gastrointestinal adverse event rate of 12%[4] and 15%.[5]

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Study Conclusions[1]

1. This is the first study to **compare Librela** to an **NSAID for the control of OA-related pain** in dogs.

2. The results indicate both products are equally effective in **managing OA pain, and efficacy** improved with both products over time.

3. In this study, Librela was associated with **fewer adverse events**. Veterinarians should rely on product labels when making clinical decisions.

IMPORTANT SAFETY INFORMATION: For use in dogs only. Women who are pregnant, trying to conceive or breastfeeding should take extreme care to avoid self-injection. Hypersensitivity reactions, including anaphylaxis, could potentially occur with self-injection. Librela should not be used in breeding, pregnant or lactating dogs. Librela should not be administered to dogs with known hypersensitivity to bedinvetmab. The most common adverse events reported in a clinical study were urinary tract infections, bacterial skin infections and dermatitis. See full Prescribing Information at LibrelaPI.com.

References: 1. Innes et al: A randomised, parallel group clinical trial comparing bedinvetmab to meloxicam for the management of canine osteoarthritis. European Society of Veterinary Orthopaedics and Traumatology Meeting Proceedings, 2024, Lisbon, Portugal. **2.** Librela Prescribing Information. Zoetis Inc. March 2023. **3.** Metacam Package Insert. [Oral Suspension]. June 2022. Boehringer Ingelheim. **4.** Nell T, Bergman J, Hoeijmakers M, et al. Comparison of vedaprofen and meloxicam in dogs with musculoskeletal pain and inflammation. *J Small Animal Practice*. 2002;43(5):208-212. **5.** Walton MB, Cowderoy EC, Wustefeld-Janssens B, et al. Mavacoxib and meloxicam for canine osteoarthritis: a randomised clinical comparator trial. *Vet Rec*. 2014;175(11):280.

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