# Librela™ (bedinvetmab injection)

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

Innes JF, Lascelles BDX, Bell D, et al. A randomised, parallel-group clinical trial comparing bedinvetmab to meloxicam for the management of canine osteoarthritis. *Front Vet Sci.* 2025;12:1502218.

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### Study Objectives[1]

- Compare efficacy
- Compare safety

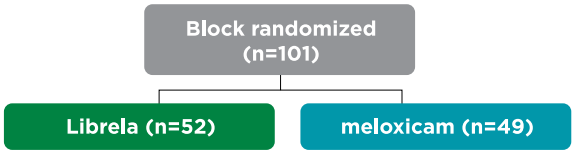
### Study Benefits and Limitations[1]

- 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 included measures to ensure compliance with dosing*

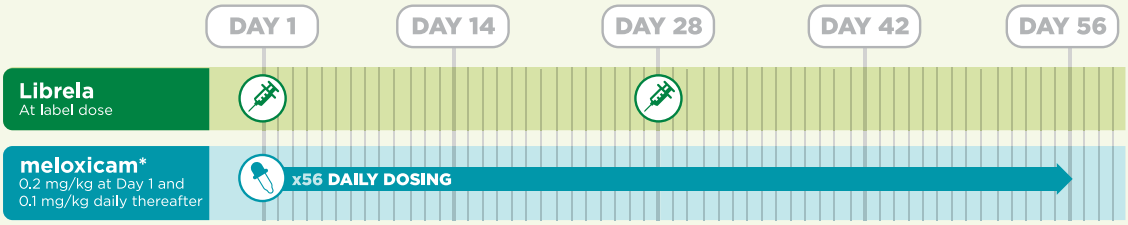
### Study Design and Methods[1]

**Prospective, multicenter, open-label randomized clinical trial**

Study design was established following 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




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

†COI and VCA at each visit.

VCA=Veterinary Categorical Assessment.

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# Efficacy Results

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

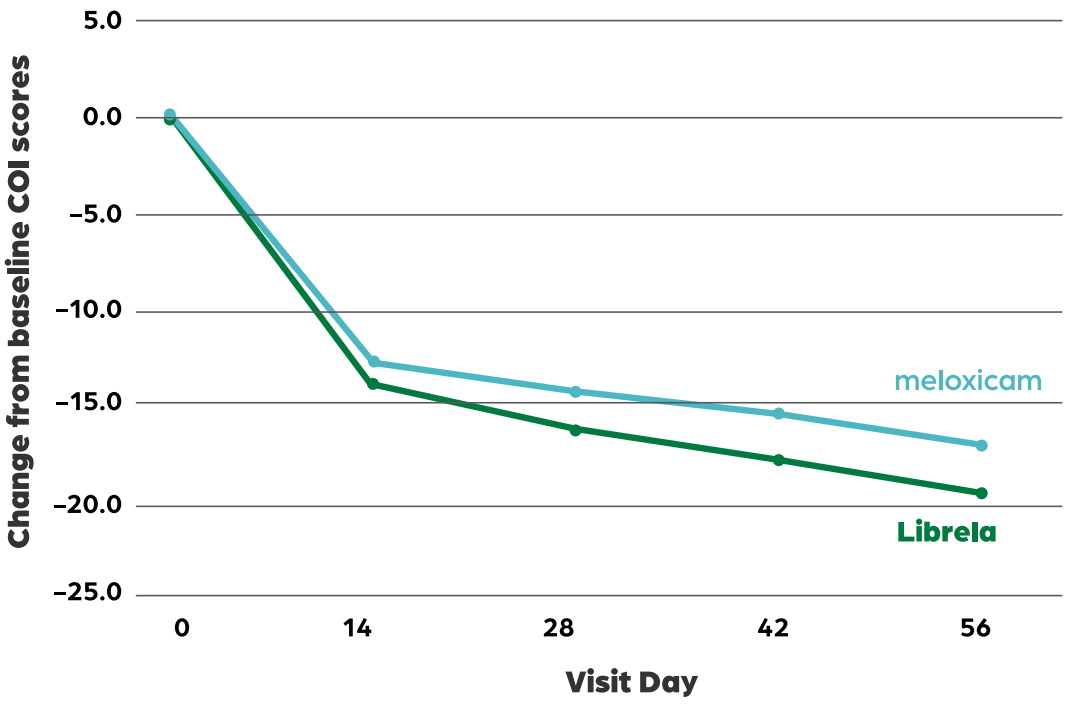
These results provide additional information on the efficacy of Librela, along with comparative data, providing veterinarians with additional insights when selecting treatment options for dogs with OA pain.

### Effective pain management[1]

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

- Librela showed equivalent efficacy to meloxicam at all timepoints measured
- Librela demonstrated greater numerical improvement than meloxicam from baseline over time (although the difference was not statistically significant)

**Change in Canine Orthopedic Index (COI)**




Librela, n=52; meloxicam, n=49.

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# Safety Results

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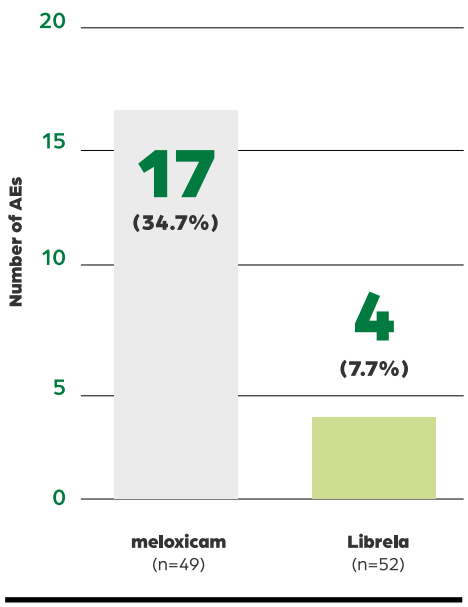
## In this clinical study, Librela was associated with fewer adverse events than meloxicam[1]

- The Librela-treated group had 4 events vs 17 in the meloxicam group
- Of the meloxicam events, 8 of the 17 were GI tract disorders, including diarrhea and vomiting
- In this study, neurologic adverse events were reported in 3 dogs in the meloxicam-treated group and 0 dogs in the Librela-treated group. However, adverse events reports do not necessarily equal causality*

| System organ class clinical sign (VeDDRA) | Group | |
|---|---|---|
| **Clinical Observation** | **meloxicam** (n=49) | **Librela** (n=52) |
| Any AE* | 17 | 4 |
| Digestive tract disorders *(eg, diarrhea, emesis)* | 8 | 0 |
| Neurological disorders† *(eg, ataxia)* | 3 | 0 |
| Musculoskeletal disorders *(eg, lameness, joint pain)* | 3 | 2 |
| Behavioral disorders *(eg, aggression)* | 1 | 0 |
| Skin and appendages disorders *(eg, pruritus, dermatitis)* | 1 | 1 |
| Systemic disorders *(eg, polydipsia, lethargy)* | 1 | 1 |

**Adverse events (AEs)* reported in the study**




*Adverse events reports do not necessarily equal causality. Data are presented as n (%); n represents the number of all dogs (all animals enrolled). Occurrence is calculated on a per-animal basis; regardless of how many observations of the same AE are recorded for a dog, only a single observation contributes to the occurrence calculation.
†Neurologic disorders included 2 dogs with ataxia/loss of proprioception and 1 with vestibular disease.

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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% |

Adverse events reported most frequently for Librela based on post-approval drug experience reporting include: ataxia, anorexia, lethargy, emesis, polydipsia, polyuria/pollakiuria (January 2025).

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## 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 Takeaways[1]

Librela (bedinvetmab injection)

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 were 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.

**LIBRELA 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 JF, Lascelles BDX, Bell D, et al. A randomised, parallel-group clinical trial comparing bedinvetmab to meloxicam for the management of canine osteoarthritis. *Front Vet Sci*. 2025;12:1502218. **2.** Librela Prescribing Information. Zoetis Inc. January 2025. **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 Pract*. 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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