

5 December 2025 EMADOC-1700519818-2668331 Committee for Veterinary Medicinal Products (CVMP)

## Summary of opinion<sup>1</sup> (post-authorisation)

## Dexdomitor

## International non-proprietary name (INN): dexmedetomidine

On 4 December 2025, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion<sup>2</sup>, recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product Dexdomitor. The marketing authorisation holder for this veterinary medicinal product is Orion Corporation.

Dexdomitor is currently authorised as solution for injection for use in dogs and cats. The variation concerns change(s) to therapeutic indication(s) – addition of a new therapeutic indication or modification of an approved one for Dexdomitor 0.5 mg/ml solution for injection: to be administered intravenously as a constant rate infusion (CRI) in dogs and cats as part of a multimodal protocol during inhalation anaesthesia. Additionally, the product information has been aligned with version 9.1 of the QRD template.

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC), for which an updated version reflecting the changes will be published in the Union Product Database (UPD) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

<sup>&</sup>lt;sup>2</sup> Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.



<sup>&</sup>lt;sup>1</sup> Summaries of opinion are published without prejudice to the Commission Decision.