

IPAR



**Publicly Available Assessment Report for a
Veterinary Medicinal Product**

Domosedan 10 mg/ml solution for injection for horses and cattle

PRODUCT SUMMARY

EU Procedure number	IE/V/0575/001/MR
Name, strength and pharmaceutical form	Domosedan 10 mg/ml solution for injection for horses and cattle
Active substance(s)	Detomidine (as detomidine hydrochloride)
Applicant	Orion Corporation Orionintie 1 FI-02200 Espoo Finland
Legal basis of application	Full application (Article 12(3) of Directive No 2001/82/EC)
Date of completion of SPC harmonisation procedure	10/04/2024
Target species	Horses and cattle
Indication for use	Sedation and analgesia in horses and cattle during various examinations and treatments, and in situations where handling of animals will be facilitated by administration of the veterinary medicinal product. For premedication before administration of injectable or inhalation anaesthetics.
ATCvet code	QN05CM90
Concerned Member States	

PUBLIC ASSESSMENT REPORT

Due to the date of authorisation of this product no public assessment report is available. Please be referred to the post authorisation procedures section.

VI. POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. The current SPC is available in the Union Product Database (UPD).

This section contains information on significant changes, which are important for the quality, safety or efficacy of the VMP and which have been made after 27 January 2022. Please be aware that changes to the product introduced before Regulation (EU) 2019/6 started to apply, will not be listed below.

Summary of change IE/V/0891/SPC/001	Approval date 10/04/2024
Harmonisation of the summary of product characteristics for a reference veterinary medicinal product, in accordance with Article 70 of Regulation (EU) 2019/6. The VMP 'Domosedan 10 mg/ml solution for injection' was accepted as a suitable reference veterinary medicinal product for SPC harmonisation as defined in Article 69, as follows: '(a) reference veterinary medicinal products which have the same qualitative and quantitative composition of their active substances and the same pharmaceutical form and for which marketing authorisations have been granted in accordance with Article 47 in different Member States for the same marketing authorisation holder.'	