Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Federal Office of Consumer Protection and Food Safety
Gerichtstraße 49
13347 Berlin
(Germany)

POST AUTHORISATION INFORMATION

FOR A VETERINARY MEDICINAL PRODUCT

Catosal 100 mg/ml + 0.05 mg/ml solution for injection for cattle, horses and dogs

Date: 05 April 2024

PRODUCT SUMMARY

EU procedure number	DE/V/0390/001
Name, strength and pharmaceutical form	Catosal 100 mg/ml + 0.05 mg/ml solution for injection for cattle, horses and dogs
Marketing Authorisation Holder	Elanco GmbH Heinz-Lohmann-Straße 4 27472 Cuxhaven Germany
Active substance(s)	Cyanocobalamin Butafosfan
ATC vetcode	QA12CX99
Target species	Cattle Horses Dogs
Indication for use	<u>All target species:</u> Supportive treatment and prevention of hypophosphatemia and/or cyanocobalamin (vitamin B_{12}) deficiency. <u>Cattle:</u> Supportive treatment to restore rumination following surgical treatment of displaced abomasum associated with secondary ketosis. Complementary treatment of parturient paresis in addition to Ca/Mg therapy. Prevention of ketosis development, if administered before calving. <u>Horses:</u> Adjunctive therapy in horses suffering from muscular exhaustion.

PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

SUMMARY OF ASSESSMENT

Legal basis of original application*	Legal basis reviewed according to Acquis communautaire
Dossier substantiated by proprietary data	Qualified for data protection: no[1]
Date of completion of the original mutual recognition procedure	SPC harmonisation of reference VMP with subsequent transfer of national authorisations to mutual recognition procedure (MRP). Date of MRP transfer: 29/07/2024
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	13/05/2005
Concerned Member States for original procedure	AT, BE, BG, CY, CZ, GR, ES, FR, HR, HU, NL, PL, PT, RO, SI, SK, LU, IT
Concerned Member States for subsequent recognition procedure	Not applicable.
Withdrawn CMS during original mutual recognition procedure	Not applicable.

Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES. Additionally, detailed information on protection periods has only been published in puAR since 09.02.2026.

[1] Please note that the start of the period of protection is the date when the first marketing authorisation was granted in the Union (please refer to Guidance to Applicants – Veterinary medicinal products C/2024/1443 as amended by C/2024/90009 Corrigendum to Commission Notice – Guidance to Applicants – Veterinary Medicinal Products). For further information, please check the UPD.

GENERAL INFORMATION

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

POST-AUTHORISATION PROCEDURES

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.

Please note that for VMPs that were transferred to MRP after SPC harmonisation, the section "Changes to Part 2 of the dossier (quality)" contains only information on significant changes important to quality which have been made starting from Part II harmonisation, whereas section "Changes to Part 3 and/or Part 4 of the dossier (safety/efficacy)" contains only information on significant changes important to safety or efficacy of the VMP which have been made starting from the respective SPC harmonisation procedure.

Sequence of significant variations

Changes to Part 2 of the dossier (quality)

Summary of change (Application number)	End of procedure
F.V.b.1.b QUALITY CHANGES - Changes to a marketing authorisation resulting from other regulatory procedures - Harmonisation of the quality dossier - Harmonisation of the quality dossier after a SPC harmonisation procedure (DE/V/xxxx/WS/147)	27/05/2024
F.I.d.1.c - Change in the retest period/storage period of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Extension of a retest period supported by real time data F.II.b.3.h - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Change in the holding time of an intermediate or bulk product (DE/V/0390/A/001/G)	09/07/2025

Changes to Part 3 and/or Part 4 of the dossier (safety/efficacy)

Summary of change (Application number)	Supporting information	End of procedure
SPC harmonisation of a reference VMP in accordance with article 70 of Regulation (EU) 2019/6 (DE/V/0390/SPC/001)	Appropriate existing data (proprietary/bibliographic) to support aspects that go beyond the common denominator in accordance with Article 8 of Regulation (EU) 2019/6 for harmonisation of dossier in RMS and CMS. Qualified for data protection: no[2]	05/04/2024

[2] Please note that the period of protection starts counting from the date of the first amendment of the marketing authorisation in the EU (please refer to Guidance to Applicants – Veterinary medicinal products C/2024/1443 as amended by C/2024/90009 Corrigendum to Commission Notice – Guidance to Applicants – Veterinary Medicinal Products).