Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

PROPALIN, 40.28 mg/ml, Syrup for Dogs

Vm 06462/3010

15 September 2026	Changes to the summary of the PSMF not already covered elsewhere in this Annex.
04 August 2026	Clarification of the form 'hydrochloride' for dose calculation in section 2. Addition of a footnote for proteinuria in AE section.
27 March 2026	One-off alignment of the product information with version 9.1 of the QRD template.
30 July 2025	Change in shape or dimensions of the container closure.
29 July 2025	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
25 July 2025	Change of legal entity of the Marketing Authorisation Holder from, Vetoquinol UK Limited, Steadings Barn, Pury Hill Business Park, Nr. Alderton, Towcester, Northamptonshire, NN12 7LS to Vetoquinol SA, 34 Rue de Chene Sainte-Anne, Magny-Vernois, 70200 Lure, France (NI only).
10 June 2024	Introduction of a new manufacturer of the active substance Phenylpropanolamine supported by an ASMF.
04 May 2024	Changes in SPC sections 4.5, 4.6 and 4.9.
14 December 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (NI)
27 October 2023	The specification limit for density has been changed at release and at shelf life.
25 April 2023	Replacement of the bottle insert of the finished product.
29 September 2021	Change in storage conditions of the finished product. From: Do not store above 25°C. Do not refrigerate. To: Do not store above 25°C.Keep the bottle in the outer carton in order to protect from light.
21 April 2020	Changes to the labelling and package leaflet.
12 November 2019	Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Change to a test procedure for the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Change in the specification limits of the finished product.
04 February 2019	Change in RMS from UK to ES.
07 September 2018	Change in the address of the marketing authorisation holder from Vétoquinol UK Limited, Vetoquinol House, Great Slade, Buckingham Industrial Park, Buckingham, MK18 1PA to Vetoquinol UK Limited, Steadings Barn, Pury Hill Business Park, Nr Alderton, Towcester, Northanmptonshire, NN12 7LS.
09 October 2017	Change to part of the (primary) packaging material not in

	contact with the finished product formulation. Minor change in the manufacturing process of the finished product.
30 August 2017	Change in the address of the marketing authorisation holder in Germany from Vetoquinol GmbH, Parkstr. 10, D - 88212 Ravensburg to Vetoquinol GmbH, Reichenbachstr. 1, D-85737 Ismaning.
23 July 2008	Renewal, UK as RMS.
31 January 2006	Change of Marketing Authorisation Holder and distributor address.
26 January 2005	Repeat use procedure – UK as RMS.
10 May 2004	Change in the test procedure of the finished product.
30 March 2004	Change of packaging details.
05 December 2003	Change of administration device.
20 March 2003	EUDE, UK as RMS.
28 March 2003	Renewal.
28 June 2002	Variation to update licence particulars.
26 March 2002	Variation to update licence particulars (Part II).
26 March 2001	Variation to update licence particulars (Target Species Tolerance).
09 February 2001	Variation to update licence particulars (Repeat Dose Pharmacokinetics).
06 February 2001	Variation to update licence particulars (Clinical Trials).
23 July 1999	Change to the test procedure for the finished product.
08 April 1998	Renewal.
08 April 1998	Change to the finished product formulation.
31 March 1998	Addition of a pack size.
31 July 1997	Addition of a manufacturer/assembler of dosage form.
31 July 1997	Extension of shelf-life.
28 June 1996	Change of name and address of PI/ATC Holder.
07 December 1995	Addition of an active substance manufacturer.