Veterinary Medicines Directorate

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# Post Authorisation Assessments

## Propalin Syrup 40 mg/ml Dogs

Vm 08007/4035

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| • | 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.<br>From: Do not store above 25°C. Do not refrigerate.<br>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.<br>Change to a test procedure for the finished product.<br>Addition of a new specification parameter to the specification with its corresponding test method of the finished product.<br>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.<br>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. |

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| • | 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. |