Veterinary Medicines Directorate

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Post Authorisation Assessments

Optimmune 2 mg/g Eye Ointment for Dogs

Vm 06376/4134

9 June 2026	Submission of an updated Ph. Eur. Certificate for an active substance.
26 May 2026	Change in the batch size (including batch size ranges) of the finished product.
01 March 2026	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
17 February 2026	Alignment of the product information with version 9.0* of the QRD templates. Update to administration instructions regarding opening the tube for the first time.
05 March 2025	Submission of a new or updated European Pharmacopoeia Certificate of Suitability from an already approved manufacturer for a non-sterile active substance.
03 January 2025	Change in legal entity of the Marketing Authorisation Holder from MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, MK7 7AJ to Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, Netherlands.
14 March 2023	Change in any part of the primary packaging material not in contact with the finished product formulation.
15 June 2022	Updated certificate of suitability for an active substance.
09 June 2021	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
18 November 2020	Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
24 July 2019	Changes to the Veterinary Medicinal Product.
29 June 2017	Change 4.6 of the SPC to reflect the updated adverse reactions (frequency and seriousness) section.
04 September 2012	Change of product name from Optimmune Opthalmic Ointment 2 mg/g Eye Ointment to Optimmune 2 mg/g Eye Ointment.
04 September 2012	Change of layout of package leaflet.
08 August 2012	Change of MAH and change in distributor.
20 April 2012	Deletion of a manufacturer and assembler of dosage form.
03 September 2010	Change in the name of the manufacturer of the active substance.
18 December 2009	Change in material used in the manufacture of the packaging of finished product.
18 December 2009	Addition of a site responsible for finished product manufacture, packaging and batch release.
16 December 2008	Changes to the SPC and product literature to bring in line with new legislation.

16 December 2008	Change of legal category from POM to POM-V.
08 December 2008	Change to test procedure of finished product.
21 March 2007	Renewal.
10 September 2002	Addition of a manufacturer of the active substance.
27 May 2002	Harmonisation of product literature.
17 July 2000	Change in dimensions of packaging.
26 July 1999	Renewal.
12 September 1997	Change in shelf-life.
14 August 1996	Change of indications.
21 June 1995	Addition of an assembler of finished product.
26 January 1995	Change in dosage instructions.