Veterinary Medicines Directorate

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Post Authorisation Assessments

Receptal 4 microgram/ml Solution for Injection

Vm 06376/5065

26 May 2026	Minor change in the manufacturing process of the finished product.
22 April 2026	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
27 November 2025	Submission of mock-ups.
14 October 2025	SPC harmonisation.
29 May 2025	Harmonisation of the quality dossier.
13 November 2024	Minor changes to an approved test procedure for the finished product.
12 November 2024	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.
16 June 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
22 February 2022	Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions.
28 April 2021	Change in name of the MAH from Intervet UK Ltd, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ.
11 June 2019	Change in the name of a manufacturer used in the manufacture of the active substance.
07 December 2017	Change in the SPC and Package Leaflet to implement the outcome of a procedure concerning PSUR.
01 August 2016	Submission of a new Ph. Eur. certificate of suitability for an active substance
28 June 2016	Submission of an updated certificate of suitability.
09 March 2016	To amend the manufacturing overage for all presentations. To change the bromobutyl rubber stoppers to Laminated halogenated bromobutyl rubber stoppers.
21 August 2014	Additional 50ml pack size of the finished product.
13 December 2012	Grouped variation: - Changes in the composition of the finished product. - Change in the manufacturing process of the finished product. - Change to in-process tests or limits of the finished product. - Changes in the specification parameters and/or limits of the finished product.

	- Changes in the test procedure of the finished product. - Changes in the shelf-life or storage conditions of the finished product.
21 April 2011	Submission of an updated EDQM certificate of suitability for a manufacturer of the active substance.
11 April 2011	Extension application to add pigs as a target species.
21 December 2010	Change to part of the primary packaging not in contact with the finished product.
21 August 2008	Changes to the SPC and product literature to bring them into line with new legislation.
21 August 2008	Change in legal category from POM to POM-V.
13 September 2007	Renewal.
24 August 2005	Change in the manufacturer of the finished product.
20 May 2005	Change of distributor for Northern Ireland.
03 December 2004	Corrections/text changes to the SPC and labels.
10 September 2003	Renewal.
13 August 2003	Alternative 10ml container shape.
03 July 2001	Additional distributor in Northern Ireland.
17 March 2000	Change in name and address of MAH.
03 August 1998	Renewal.
19 January 1998	Variation regarding fixed time insemination.
15 December 1997	Change to finished product specifications.
27 October 1997	Additional pack size.
12 September 1997	Change to therapeutic purpose.
03 February 1997	Change of name of MAH.