



## Post Authorisation Assessments

### Planate 87.5 micrograms/ml Solution for Injection

Vm 06376/3063

14 March 2026	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
24 November 2025	Submission of mock ups.
04 November 2025	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State.
01 October 2025	Change in legal entity of Marketing Authorisation Holder from MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, MK7 7AJ, United Kingdom to Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, Netherlands.
27 August 2025	CMDv SPC Harmonisation according to Articles 70 to 72 of Regulation (EU) 2019/6.
16 May 2025	Harmonisation of the Quality part of the dossier following CMDv SPC/QRD harmonisation.
07 May 2025	Change in the holding time of the finished product.
07 October 2021	Update of a test procedure to comply with the updated Ph. Eur. monograph.
12 March 2021	Change in the name of the marketing authorisation holder from Intervet UK Ltd to MSD Animal Health UK Limited.
29 October 2019	Deletion of a non-significant specification parameter of the finished product.
16 November 2016	Change to part of the (primary) packaging material not in contact with the finished product formulation. Change in pack size of the finished product. Deletion of a non-significant specification parameter of the finished product. Removal of the 10ml pack size from the pack size range. Change to a test procedure for the finished product. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions. Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product. Change of storage precaution for final product to 'Do not store above 30C'. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Change in the qualitative and quantitative composition of the

	<p>immediate packaging of the finished product.</p> <p>Change in the specification limits of the finished product.</p> <p>Change in the specification parameters and/or limits of the finished product.</p> <p>Change in the composition (excipients) of the finished product.</p>
11 July 2014	Change in the name of two manufacturing sites of starting materials.
21 March 2012	Updates to the Product Literature
18 January 2012	Change of MAH and Distributor
23 November 2010	Change of name of manufacturing site of the finished product
07 July 2010	Change of shelf life from 3 years to 2 years
29 July 2009	<p>Change of legal category from POM to POM-V</p> <p>Changes to the SPC and Product Literature to bring in line with new legislation</p>
15 May 2006	Renewal
27 January 2006	Change of withdrawal period for Meat from Pigs from 4 days to 2 days
24 May 2001	Addition of a manufacturer of the active substance
12 January 1998	Change of MAH
04 June 1997	<p>Change to formulation</p> <p>Change to manufacturer of the dosage form</p>