



Post Authorisation Assessments

Ubrolexin Intramammary Suspension for Lactating Dairy Cows Vm 61700/3019

28 November 2025	Change of legal entity of the Marketing Authorisation Holder from Boehringer Ingelheim Animal Health UK Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom to Boehringer Ingelheim Vetmedica GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germany.
15 October 2025	One-off alignment of the product information with version 9.0* of the QRD templates.
28 May 2025	Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance.
08 May 2025	Change in test procedure for the finished product: -including replacement.
28 April 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
28 September 2022	Substantial updates to an ASMF.
28 September 2021	Deletion of a non-significant parameter of an active substance.
05 February 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
24 September 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
23 May 2019	Extension of a storage period of the active substance.
06 March 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
07 November 2018	Change of MAH, from Boehringer Ingelheim Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
30 August 2017	Deletion of manufacturing site for an active substance. Deletion of manufacturing site for an active substance. Addition of a manufacturer of the active substance.
23 December 2015	Changes to DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH
24 April 2013	Change in name of the manufacturer of the finished product.
24 September 2012	Renewal procedure – Ireland as RMS.
11 January 2012	To change the address of the MAH in Spain and Portugal.
11 January 2012	To change the address of the MAH in Italy.
23 September 2010	Addition of a manufacturing site and a milling site for the

	active substance. Minor change to manufacturing process of active substance.
23 September 2010	Change in the re-test period/storage period or storage conditions of the active substance.
23 September 2010	Change to in-process tests or limits applied during the manufacture of the finished product.
3 September 2010	Change in the batch size (including batch size ranges) of the finished product.