Veterinary Medicines Directorate

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Post Authorisation Assessments

Anofline Lactating Cow Intramammary Suspension

•	08 August 2019	Change in the invented name of the veterinary medicinal product from Noroclav Lactating Cow Intramammary Suspension to Anofline Lactating Cow Intramammary Suspension.
•	30 July 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	27 July 2016	Submission of an updated certificate of suitability.
•	24 February 2016	Deletion of a manufacturing site of the active substance. Submission of an updated certificate of suitability.
•	21 January 2016	Milk withdrawal period in cattle increased from 60 hours to 84 hours
•	23 December 2015	Submission of a new or updated Ph. Eur. certificate of suitability.
•	10 November 2014	Changes to an existing pharmacovigilance system as described in the DDPS
•	26 November 2013	Variation concerning the submission of Ph. Eur. Certificates of Suitability for the Active Substance.
•	12 January 2012	Variation to change the Distributor address.
•	03 December 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	16 June 2008	Renewal.
•	28 April 2008	Submission of an updated Certificate of Suitability for the Active Substance.
•	09 April 2008	Variation concerning the deletion of an Active Substance manufacturer.
•	09 May 2007	Addition of an Active Substance Manufacturer.
•	09 May 2007	Addition of an Active Substance Manufacturer.
•	20 February 2007	Variation to transfer the legal category from POM to POM-V.
•	22 April 2004	Variation to change the specification of an excipient.
•	26 June 2003	Variation concerning the submission of Certificate of Suitability Revisions.