Veterinary Medicines Directorate

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Post Authorisation Assessments

Ampredclav Intramammary Suspension for Lactating Cows

•	01 July 2020	Change in the invented name of the veterinary medicinal product from Combiclav Lactating Cow Intramammary Suspension to Ampredclav Intramammary Suspension for Lactating Cows.
•	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.
•	12 July 2016	Submission of a new certificate of suitability.
•	09 March 2016	Deletion of a manufacturing site of an active substance that uses a Ph. Eur. certificate of suitability Submission of a new or updated Ph. Eur. certificate of suitability
•	26 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
•	23 April 2014	Change of distributor.
•	22 November 2013	Submission of an updated Ph. Eur. Certificate of Suitability for an already approved active substance manufacturer.
•	23 December 2008	Renewal
•	24 July 2008	Changes to the SPC and Product Literature to bring in line with new legislation
•	28 April 2008	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	09 April 2008	Deletion of a manufacturer of the active substance
•	13 June 2007	Addition of a manufacturers of the active substances
•	28 March 2007	Change of legal category from POM to POM-V
•	24 August 2005	Addition of an indication for combined use with Combiclav injection
•	12 August 2004	Change of finished product composition