Veterinary Medicines Directorate

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Post Authorisation Assessments

Denagard 2% w/w Premix for Medicated Feed for Pigs, Chickens, Turkeys and Rabbits

•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	31 January 2018	Minor changes to an approved test procedure of the finished product.
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	10 August 2016	Change in the name of a manufacturer of the finished product including manufacturer responsible for batch release
•	16 March 2016	Change in distributor details Change in legal entity
•	11 June 2015	Minor changes in the manufacturing process.
•	09 October 2014	Minor changes to the control monograph of the excipient, to comply with Ph. Eur.
•	06 March 2014	Submission of an updated Ph. Eur. Certificate of Suitability for an already approved active substance manufacturer.
•	28 February 2014	Changes to an existing pharmacovigilance system.
•	06 August 2013	Changes to comply with the update to the Ph. Eur monograph for an excipient.
•	14 May 2013	Deletion of manufacturing site responsible for batch release.
•	27 September 2012	Changes to an existing pharmocvigilance system as described in the DDPS.
•	12 June 2012	Submission of an updated Ph. Eur certificate of suitability for an already approved manufacturer of the active substance.
•	15 June 2011	Updates to the SPC and product literature in line with an EU Directive.
•	05 April 2011	Addition of a site of batch release.
•	12 August 2008	Batch control.
•	07 May 2008	Changes to bring the SPC and product literature in line with new legislation.
•	20 December 2007	Addition of a new therapeutic indication.
•	21 August 2007	Change in the ATCVet code and change of MAH and distributor address.
•	21 May 2007	Renewal.
•	16 October 2006	Submission of an updated Ph. Eur certificate of suitability for the active substance manufacturer.
•	07 September 2006	Change in the invented name of the product from Tiamutin 2% Premix to Denagard 2% Premix and to change the legal category from MFS to POM-V.

•	15 June 2006	Addition of a new manufacturer for batch release.
•	16 May 2006	Change to the formulation, change to the intermediate product and changes to the control of starting materials and packaging.
•	08 May 2006	Submission of a new Ph. Eur certificate of suitability for the active substance manufacturer.
•	23 June 2005	Renewal.
•	23 June 2005	Increase to the meat withdrawal period.
•	22 June 2005	Bring the active substance in line with the published Ph. Eur monograph for the active substance.
•	07 April 2005	To change the site of active substance manufacture.
•	02 April 2004	To change the active substance manufacturer.
•	28 September 2001	Change of distributor and change of MAH address.
•	14 April 2000	Change of manufacturing authorisation holder (MAH) from Leo Laboratories Ltd to Novartis Animal Health and change of manufacturer.
•	24 September 1997	Updates to the therapeutic indications and product literature.
•	31 July 1997	Renewal.