Veterinary Medicines Directorate

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Post Authorisation Assessments

Denagard 80% w/w Premix for Medicated Feed for Pigs, Chickens and Turkeys

•	17 August 2021	Change in the specification parameters of the active substance, and of the finished product. Change in the specification parameters of the active substance, and of the finished product.
•	03 March 2021	Changes to the SPC/product labelling/package leaflet following an Article 35 referral.
•	08 July 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Extension of a re-test period of the active substance.
•	12 March 2020	Addition of a manufacturer responsible for batch release of the finished product.
•	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.
•	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.
•	23 October 2012	Submission of an updated Ph. Eur certificate of suitability for an already approved manufacturer of the active substance.
•	27 September 2012	Changes to an existing pharmacovigilance system as described in the DDPS.
•	15 June 2011	To update the SPC and product literature following an EU Directive.
•	02 April 2009	Minor changes in the manufacturing process for the finished product.
•	18 December 2008	Batch control.
•	21 May 2008	To bring the SPC and product literature in line with new legislation.
•	28 November 2007	Change in the ATCVet code.

•	22 November 2007	Change of MAH name and address from Novartis Animal Health to Novartis Animal Health UK Limited.
•	31 October 2007	Change in the invented name of the product from Tiamutin to Denagard.
•	20 September 2007	Renewal.
•	16 October 2006	Submission of an updated Ph. Eur certificate of suitability for the active substance manufacturer.
•	08 May 2006	Submission of a new Ph. Eur certificate of suitability for the active substance manufacturer.
•	10 November 2005	Change to the formulation.
•	23 June 2005	Increase to the meat withdrawal period.
•	23 June 2005	Renewal.
•	22 June 2005	Publication of the Ph. Eur monograph for the active substance.
•	10 December 2004	To change the active substance manufacturer.
•	11 November 2004	To change the name of a manufacturer.
•	02 April 2004	To change the active substance manufacturer.
•	13 May 2002	Submission of a TSE Certificate
•	28 September 2001	Change of MAH address.
•	11 April 2000	Change of manufacturing authorisation holder (MAH) from Leo Laboratories Ltd to Novartis Animal Health.
•	24 December 1997	Renewal.