Veterinary Medicines Directorate

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Post Authorisation Assessments

Denagard 12.5% w/v Concentrate for Oral Solution

Vm 00879/4052

•	07 April 2022	Editorial changes including change in name of an alternative active substance QC testing site.
•	30 March 2022	Change in the name of a manufacturer used in the manufacture of the active substance.
•	21 December 2021	Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product. Deletion of a non-significant in-process test applied during the manufacture of the finished product. Addition of new tests and limits applied during the manufacture of the finished product.
•	02 November 2021	Addition of a new specification parameter to the specification with its corresponding test method of the immediate packaging of the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	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.
•	17 February 2021	Updated Ph. Eur Certificate of Suitability. Addition of a test procedure for the active substance. Changes to quality control testing arrangements for the active substance.
•	22 October 2020	Change in the address of the Marketing Authorisation Holder from Elanco Europe Ltd, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom to Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	05 June 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Introduction of a re-test period of the active substance.
•	16 July 2019	Addition of a site where batch control/testing takes place.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	13 February 2019	Deletion of a non-significant specification parameter of the finished product.

		Changes to a test procedure for the finished product.
•	13 February 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	06 July 2017	Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	16 March 2016	Change in distributor details Change in legal entity
•	15 December 2015	Submission of a new certificate of suitability.
•	12 March 2015	Change in batch size of the finished product.
•	21 August 2014	Grouped variation to update the packaging information in the dossier.
•	11 July 2014	Removal of 20ml measuring device provided with 1L bottles.
•	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 September 2013	Change in test procedure performed on the finished product. Change in specification of the finished product.
•	05 April 2013	Batch control.
•	05 March 2013	Batch control.
•	27 September 2012	Changes to the Pharmacovigilance system that do not change the DDPS.
•	22 August 2012	Batch control.
•	27 July 2012	Batch control.
•	12 June 2012	Submission of an updated Ph. Eur. Certificate of Suitability for the active substance.
•	27 April 2012	Batch control.
•	16 June 2009	Minor changes to the manufacturing process of the finished product. Replacement of a manufacturing site for all of the manufacturing process of the finished product except batch release.
•	02 June 2009	Addition of a manufacturer for batch release including batch control.
•	06 February 2009	Minor change to test performed on the finished product.
•	29 May 2008	Changes to the SPC and Product Literature to bring in line with new legislation.
•	21 August 2007	Change of address of MAH and distributor. Change in ATC code.
•	12 January 2007	Renewal.
•	20 December 2006	Addition of dosing device to 1L pack size.
•	23 November 2006	Change of product name from ‘Tiamutin 12.5% Solution’ to ‘Denagard 12.5% w/v Concentrate for Oral Solution’.
•	09 November 2006	Change of legal category from POM to POM-V.
•	16 October 2006	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer.
•	22 June 2006	Addition of a manufacturer responsible for batch release of the finished product.

•	14 June 2006	Change in test procedure performed on the finished product.
•	08 May 2006	Submission of a Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer.
•	22 February 2006	Change in composition of the immediate packaging material.
•	22 June 2005	Changes to comply with Ph. Eur.
•	07 April 2005	Change of manufacturing site for the active substance.
•	30 November 2004	Extension to add chickens, turkeys and racing pigeons to the target species.
•	21 April 2004	Change of withdrawal period for pigs from 24 hours to 2 days. Renewal.
•	02 April 2004	Change of manufacturer of the active substance.
•	07 March 2002	Change of manufacturer of the dosage form.
•	28 November 2001	Introduction of package insert.
•	18 September 2001	Change of distributor.
•	24 July 2000	Change of MAH.
•	19 January 1998	Update of licence particulars.
•	29 August 1997	Renewal.
•	18 August 1997	Change of safety warnings.
•	19 August 1996	Additional manufacturer of the dosage form.