Veterinary Medicines Directorate

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Post Authorisation Assessments

Denagard 200 mg/ml Solution for Injection

Vm 00879/4053

•	20 February 2024	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible.
•	20 February 2024	Extension of the re-test period of the active substance supported by real time data. Change in the storage conditions of the active substance.
•	19 June 2023	Change in name of a manufacturer for quality control of the finished product.
•	10 May 2023	Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance. Minor change to the restricted part of an Active Substance Master File. Change in the re-test period/storage period of the active substance.
•	08 April 2022	Tightening of specification limits of the finished product. Deletion of a non-significant specification parameter of the finished product. Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	11 March 2022	Changes to the withdrawal period of the veterinary medicinal product.
•	03 March 2022	Minor changes to an approved test procedure 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.
•	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.
•	12 October 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. 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.
•	28 July 2020	Changes to the withdrawal period of the veterinary

		medicinal product from 21 days to 28 days.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	20 November 2018	Addition of a site where batch control/testing takes place. Addition of a site where batch control/testing takes place. Addition of a site where batch control/testing takes place. Changes to a test procedure for the finished product. Addition of a manufacturing site of the finished product. Change of a test procedure for the finished product. Changes in the manufacturing process of the finished product.
•	14 December 2017	Addition of a secondary packaging site of the finished product. Changes to the labelling or package leaflet.
•	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
•	03 November 2015	An increase in the withdrawal period for meat and offal from 14 days to 22 days
•	28 February 2014	Changes to an existing pharmacovigilance system.
•	14 May 2013	Deletion of a manufacturing site responsible for batch release
•	07 November 2012	Change of shelf life from 3 years to 5 years
•	27 September 2012	Changes to an existing pharmacovigilance system that do not affect the DDPS
•	12 June 2012	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	22 February 2012	Addition of a site for batch release of the finished product
•	03 December 2008	Change to test methods performed on the finished product
•	05 June 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
•	13 December 2006	Change of name of the product from ‘Tiamutin 200 Injection’ to ‘Denagard 200mg/ml Solution for Injection’
•	16 October 2006	Addition of a manufacturer responsible for batch release of the finished product
•	12 July 2006	Change of packaging materials
•	08 May 2006	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	08 March 2006	Change of specification of the finished product
•	13 February 2006	Change of legal category from POM to POM-V
•	29 November 2005	Renewal
•	24 October 2005	Change of withdrawal period from 10 days to 14 days Renewal
•	22 June 2005	Update to bring in line with Ph. Eur.

•	07 April 2005	Change of manufacturing site of the active substance
•	02 April 2004	Change of name of manufacturer of the active substance
•	29 August 2001	Change of distributor
•	31 January 2001	Change of manufacturing site of the dosage form
•	24 July 2000	Change of MAH
•	26 February 1998	Renewal
•	09 December 1997	Corrections to the SPC and Product Literature
•	18 March 1996	Change of name of manufacturer of the finished product