Veterinary Medicines Directorate

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Post Authorisation Assessments

Prascend 1 mg Tablets for Horses

Vm 08327/5036

•	08 June 2023	Change(s) in the name of a qualified person for pharmacovigilance (QPPV). (NI) Introduction of a summary of the PSMF. (NI)
•	12 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	01 December 2020	Changes to SPC and product information following a periodic safety update report (PSUR).
•	19 October 2020	Change in the number of units (tablets) in a pack within the range of the currently approved pack sizes of the finished product. Addition of a manufacturer responsible for batch release including batch control/testing. Change in the fill volume of the finished product. Change in the fill volume of the finished product.
•	17 August 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	24 September 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	17 September 2019	Change in the name of a manufacturer of the finished product. Change to an approved stability protocol. Deletion of a non-significant specification parameter of the finished product
•	25 July 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	06 March 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	07 November 2018	Change of MAH, from Boehringer Ingelheim Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
•	27 October 2015	Variation to extend the shelf life of the finished product from 2 to 3 years. Deletion of a non-significant specification parameter (uniformity of mass)
•	12 November 2014	Renewal.
•	24 December 2013	Deletion of an active substance manufacturing site.
•	12 December 2013	Changes to the finished product specification limits.
•	15 May 2012	Harmonisation of product literature between the original and new Concerned Member States following a Repeat

		Use procedure.
•	14 March 2012	Submission of a new or updated Ph. Eur. Certificate of suitability.
•	21 December 2011	Repeat Use Comm
•	14 June 2011	To modify the SPC due to new quality, pre-clinical, clinical or pharmacovigilance data
•	14 June 2011	To make editorial changes to the SPC
•	15 July 2010	To replace the present primary and secondary packaging site.
•	11 March 2010	DCP – UK as CMS.
•	27 January 2010	Addition of 60 and 160 tablet pack sizes.
•	05 January 2010	Change to the imprints on the tablets.
•	05 January 2010	Replacement of batch release site.