Veterinary Medicines Directorate

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Post Authorisation Assessments

Pro Dynam Oral Powder 1 g Phenylbutazone Per Sachet

Vm 24883/4000

•	12 February 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	15 December 2010	Change of distributor.
•	05 November 2009	Change in the site responsible for filling and packaging of the finished product.
•	02 July 2009	Changes to colour on the packaging (carton box).
•	20 May 2009	Renewal.
•	19 March 2009	Change in the name of the MAH, manufacturer of the finished product and batch release site.
•	23 September 2008	Harmonisation of SPC.
•	13 August 2008	Change in the withdrawal period in horses.
•	27 June 2008	Change in the distributor.
•	08 May 2006	Change in batch release arrangements.
•	03 May 2006	Addition of a manufacturing site.
•	18 April 2006	Change to test procedure for the active substance.
•	09 November 2005	Replacement of the primary packaging site.
•	25 July 2005	Change of MAH.
•	30 June 2005	Additional distributor.
•	05 May 2005	Addition of an assembler of dosage form.
•	14 January 2005	Change to site of batch release.
•	29 September 2004	Renewal.
•	20 July 2004	Change in the manufacturer of the active substance.
•	29 May 2003	Removal of a warning from the SPC.
•	09 September 1999	Change of test methods.
•	07 June 1999	Renewal.
•	29 August 1997	Change of address of assembler.
•	26 June 1997	Addition of an assembler.