Veterinary Medicines Directorate

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Post Authorisation Assessments

Sedivet 10 mg/ml Solution for Injection for Horses

Vm 08327/4302

•	12 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	11 April 2022	Reduction of the shelf life of the finished product as packaged for sale from 5 years to 3 years.
•	08 April 2022	Deletion of manufacturing site for an active substance.
•	07 October 2020	Reduction in the retest period of the active substance.
•	31 March 2020	Changes to the labelling and package leaflet.
•	22 August 2019	Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process. Widening of the specification limits of a starting material used in the manufacturing process of the active substance.
•	09 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.
•	10 July 2018	Addition of a manufacturer of the active substance.
•	12 June 2017	Addition of a site where testing takes place. Addition of a site where testing takes place.
•	31 December 2013	Variation to update and harmonize test procedures and parameters and limits for the finished product.
•	12 October 2012	Addition of a new specification parameter and it's corresponding test method for the immediate packaging of the finished product.
•	01 March 2012	Grouped variation to delete a site of assembly.
•	09 February 2012	Deletion of an assembler, manufacturer of the finished product, and manufacturer of the active substance.
•	22 December 2009	Variation to submit an updated SPC and package leaflet according to the current CMD(v) QRD template. Also to make minor editorial changes.
•	01 May 2009	Variation to extend the active substance retest period.
•	25 May 2006	Variation to update the SPC/Labelling in line with the Veterinary Regulations. 2005. Transfer of the legal category.
•	16 January 2006	Variation to update the specification of a starting material.
•	21 December 2005	Renewal.
•	17 November 2005	Variation to change the specification of the active substance.

•	25 June 2003	Variation to change the name and address of the manufacturer and assembler.
•	10 December 2002	Renewal.
•	12 September 2002	Harmonisation of the SPC and Labelling.
•	29 January 2002	Renewal.
•	04 January 2002	Change to the product withdrawal period.
•	26 October 2001	Variation concerning the manufacturer of the dosage form.
•	18 June 2001	Variation concerning the manufacturer of the dosage form.
•	04 April 2000	Variation to change the name of the manufacturer of dosage form and the active substance.
•	10 November 1998	Variation concerning the route of synthesis of the active substance.
•	23 October 1998	Change in the name of a manufacturer.
•	21 May 1998	Variation concerning the site of secondary assembly.
•	21 May 1998	Variation concerning the site of secondary assembly.
•	04 April 1997	Renewal.
•	03 October 1996	Change to the product withdrawal period.
•	03 October 1996	Variation to change the FPS.
•	06 September 1996	Addition of a manufacturer.
•	28 April 1995	Change to the safety warnings.