



Post Authorisation Assessments

Sedivet 10 mg/ml Solution for Injection for Horses Vm 04491/3040

28 August 2025	Change of legal entity of the Marketing Authorisation Holder from Boehringer Ingelheim Animal Health UK Limited to Boehringer Ingelheim Vetmedica GmbH.
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 its 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.