Veterinary Medicines Directorate

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Post Authorisation Assessments

Planipart Solution for Injection 30 micrograms/ml

Vm 08327/4299

•	12 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	07 February 2022	Deletion of manufacturing site for a finished product.
•	05 August 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	04 February 2020	Changes to the labelling and/or package leaflet.
•	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.
•	16 January 2018	Submission of a new Ph. Eur. certificate of suitability for an active substance excipient from a new manufacturer. Introduction of a re-test period of the active substance.
•	02 August 2017	Addition of a site where batch control/testing takes place Addition of a site where batch control/testing takes place
•	20 July 2016	Addition of a QC site for the finished product.
•	16 September 2015	Submission of an updated certificate of suitability.
•	21 February 2014	Addition of manufacturing sites for testing, batch release and secondary packaging. Changes to the manufacturing process and changes to tests on the finished product.
•	09 September 2013	Deletion of manufacturing sites for primary and secondary assembly
•	26 April 2013	Change of batch size Addition of an in-process test procedure performed during the manufacture of the finished product Changes to in-process controls
•	08 November 2012	Introduction of a new specification parameter to the specification of the finished product
•	04 September 2012	Addition of a test method performed on the active substance Change to specification of the active substance
•	01 March 2012	Deletion of a manufacturing site of assembly
•	09 February 2012	Deletion of a manufacturing site of the active substance
•	11 May 2011	Submission of an updated Ph. Eur. Certificate of Suitability for the active substance
•	03 November 2009	Minor change to Product Literature
•	23 October 2008	Renewal
•	29 August 2008	Change of withdrawal period for Milk from Cattle from 5 days to 60 hours, or 5 milkings

•	24 July 2008	Change of withdrawal period for Meat and offal from Cattle from 6 days to 14 days Deletion of a route of administration
•	12 March 2008	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance
•	16 January 2007	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	22 September 2005	Changes to comply with Ph. Eur.
•	28 April 2004	Change of shelf life from 5 years to 3 years
•	22 August 2003	Change of name of manufacturer and assembler of the dosage form Change of name of manufacturer of the active substance
•	16 October 2001	Addition of manufacturer of the active substance
•	11 October 2001	Change to specification of the active substance
•	04 April 2000	Change of name of manufacturing site of the finished product
•	25 October 1999	Renewal
•	20 May 1998	Change of name of manufacturing site of assembly of the dosage form