Veterinary Medicines Directorate

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Post Authorisation Assessments

Vetmedin 5 mg Hard Capsules

Vm 08327/4316

•	23 August 2023	Introduction of a new site of micronisation for the manufacturer of the active substance.
•	18 August 2023	Updated Ph. Eur. CEP from an already approved manufacturer for an active substance.
•	27 June 2023	Submission of a new Ph. Eur. TSE CEP for a non-sterile: – active substance.
•	13 April 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	21 December 2021	Introduction of a new site of manufacture. Change in the address of a manufacturer used in the manufacture of the active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	05 May 2020	Deletion of Ph. Eur. TSE certificates of suitability for an excipient. Submission of an updated Ph. Eur. TSE certificate of suitability for an excipient from an already approved manufacturer. Submission of an updated Ph. Eur. TSE certificate of suitability for an excipient from an already approved manufacturer. Submission of an updated Ph. Eur. TSE certificate of suitability for an excipient from an already approved manufacturer.
•	09 November 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	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.
•	19 July 2018	Submission of a new Ph. Eur. TSE certificate of suitability for a starting material used in manufacturing process from an already approved manufacturer. Submission of a new Ph. Eur. TSE certificate of suitability for a starting material used in manufacturing process from an already approved manufacturer. Submission of a new Ph. Eur. TSE certificate of suitability for a starting material used in manufacturing process from an already approved manufacturer. Submission of a new Ph. Eur. TSE certificate of

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•	03 August 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer
•	20 September 2016	Additional manufacturing site for primary packaging. Additional manufacturing site for secondary packaging.
•	13 November 2014	Deletion of a manufacturing site. Submission of a new Ph. Eur. Certificate of Suitability.
•	09 September 2013	Deletion of a finished product manufacturer.
•	09 September 2013	Deletion of a manufacturer.
•	26 June 2013	Submission of a new European Pharmacopoeia Certificate of Suitability for a new active substance manufacturer.
•	15 March 2012	Deletion of an active substance manufacturer, assembler of dosage form, and manufacture of dosage form. Deletion of a manufacturer as a secondary assembler.
•	15 February 2012	Amendment to section 5.1 of the SPC.
•	12 July 2011	Submission of an updated European Pharmacopoeia Certificate of Suitability for an existing active substance manufacturer.
•	12 July 2011	Submission of an updated European Pharmacopoeia Certificate of Suitability for an existing active substance manufacturer.
•	24 August 2010	Submission of an updated European Pharmacopoeia Certificate of Suitability for an existing active substance manufacturer.
•	24 August 2010	Submission of an updated European Pharmacopoeia Certificate of Suitability for an existing active substance manufacturer.
•	29 April 2010	Submission of an updated European Pharmacopoeia Certificate of Suitability for an existing active substance manufacturer.
•	29 April 2010	Submission of an updated European Pharmacopoeia Certificate of Suitability for an existing active substance manufacturer.
•	29 April 2010	Submission of an updated European Pharmacopoeia Certificate of Suitability for an existing active substance manufacturer.
•	06 October 2009	Addition of a safety warning to the SPC/Package Leaflet.
•	16 June 2009	Submission of an updated European Pharmacopoeia Certificate of Suitability for an existing active substance manufacturer.
•	16 June 2009	Submission of an updated European Pharmacopoeia Certificate of Suitability for an existing active substance manufacturer.
•	12 June 2009	Submission of a new TSE European Pharmacopoeia Certificate of Suitability for a new active substance

		manufacturer.
•	20 February 2009	Submission of a new or updated TSE European Pharmacopoeia Certificate of Suitability for an active substance manufacturer.
•	23 December 2008	Renewal.
•	01 May 2008	Extension of the active substance retest period.
•	04 October 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	12 September 2007	Addition of an alternative type of primary packaging.
•	17 May 2006	Addition of a source of an excipient.
•	17 May 2006	Addition of a source of an excipient.
•	20 April 2006	Variation to change the batch size of the finished product.
•	18 January 2006	Addition of a source for a starting material of the active substance.
•	18 January 2006	Variation to comply with the European Pharmacopoeia.
•	18 January 2006	Change in the test procedure for the active substance.
•	18 January 2006	Addition of an active substance manufacturer.
•	10 January 2006	Addition of an alternative supplier for an excipient.
•	10 January 2006	Addition of an alternative supplier for an excipient.
•	10 January 2006	Addition of an alternative supplier for an excipient.
•	15 December 2005	Submission of a new European Pharmacopoeia Certificate of Suitability for a new active substance manufacturer.
•	15 December 2005	Submission of a new European Pharmacopoeia Certificate of Suitability for a new active substance manufacturer.
•	15 December 2005	Submission of a new European Pharmacopoeia Certificate of Suitability for a new active substance manufacturer.
•	17 December 2004	Variation concerning the addition of an alternative supplier of the active substance.
•	03 November 2004	Renewal.
•	17 September 2003	Extension of the indications.
•	08 April 2004	Change to the active substance testing specification.
•	08 April 2004	Change to the active substance testing specification.
•	08 April 2004	Change to the manufacturing procedure.
•	02 December 2003	Addition of a precaution for storage.
•	25 June 2003	Variation to change the name of a manufacturer/assembler.
•	10 February 2003	Variation to change the batch size.
•	10 February 2003	Addition of a manufacturer/assembler.
•	20 June 2002	Addition of a dosage form manufacturer.
•	22 October 2001	Update Licence Particulars.
•	31 January 2001	Change to a packaging component (non-sterile).
•	30 August 2000	Addition of an active substance manufacturer.
•	20 June 2000	Change of a supplier of a starting material.
•	28 March 2000	Change of batch size of the finished product.
•	22 February 2000	Change to the manufacturing specifications.

•	22 February 2000	Addition of an assembler of dosage form.
•	25 January 2000	Addition of a container type (non-sterile).