Veterinary Medicines Directorate

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Post Authorisation Assessments

Bimectin 1% w/v Solution for Injection

Vm 50146/4002

01 May 2025	Alignment of the product information with version 9.0* of the QRD templates.
18 March 2021	Replacement of a secondary packaging site of the finished product.
23 February 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
05 September 2019	Change in the name only of a quality control testing site. Change in the name and address of a manufacturer of the finished product, also responsible for batch release. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
18 October 2018	Change of MAH, from Cross Vetpharm Group Ltd., Broomhill Road, Tallaght, Dublin 24, Ireland to Bimeda Animal Health Limited, 2 / 3 / 4 Airton Close, Tallaght, Dublin 24, Ireland.
10 April 2018	Deletion of a non-significant specification parameter of the finished product
22 December 2015	Submission of an updated certificate of suitability.
09 August 2012	Addition of a manufacturer of the active substance Submission of an updated Ph. Eur. Certificate of Suitability for an excipient.
01 March 2012	Submission of an updated Ph. Eur. Certificate of Suitability for the active substance from an already approved manufacturer
17 February 2011	Renewal
09 December 2009	Increase in withdrawal period for cattle meat and offal from 35 to 49 days
10 September 2008	Updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
15 November 2007	Increase of shelf life from 24 months to 3 years
24 October 2007	Minor change to the manufacturing process
22 December 2006	Line extension to add sheep to target species
05 November 2005	Renewal
12 September 2003	Change in batch size of the finished product
17 August 2003	Addition of a secondary site of assembly