Veterinary Medicines Directorate

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Post Authorisation Assessments

Bilosin 200mg/ml, Solution for Injection

Vm 50146/4026

•	18 March 2021	Replacement of a secondary packaging site of the finished product.
•	26 January 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	18 June 2020	Changes to the SPC/product labelling/package leaflet following an Article 35 referral.
•	02 August 2019	Change in the name of a manufacturer of active substance used in the manufacture of the active substance. Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
•	25 October 2018	Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of MAH, from Bimeda Chemicals Ltd., Broomhill Road, Tallaght, Dublin 24, Ireland to Bimeda Animal Health Limited, 2 / 3 / 4 Airton Close, Tallaght, Dublin 24, Ireland.
•	09 November 2010	Submission of a new Ph. Eur. Certificate of Suitability for an active substance manufacturer not previously approved.
•	03 December 2009	Renewal.
•	20 October 2009	Increase of withdrawal period from 39 to 46 days.
•	10 September 2008	Changes to bring the SPC and Product Literature in line with new legislation and change of legal category from POM to POM-V.
•	09 November 2006	Addition of a manufacturing site for manufacture, assembly and sterilisation of the finished product. Change in batch size and addition of a test method.
•	25 May 2004	Review.