



Post Authorisation Assessments

Bilovet 200 mg/ml Solution for Injection for Cattle and Pigs Vm 50146/4016

•	06 March 2024	Replacement of a secondary packaging site of the finished product. (NI)
•	07 August 2023	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product: - Minor change in the manufacturing process. Change to importer, batch release arrangements and quality control testing of the finished product:- Replacement or addition of a site where batch control/testing takes place - Other changes. Change to importer, batch release arrangements and quality control testing of the finished product:- Replacement or addition of a site where batch control/testing takes place - Other changes. Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product. Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability.
•	28 July 2023	Replacement of a secondary packaging site of the finished product.
•	20 July 2021	Change in the manufacturer of the active substance.
•	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.
•	22 June 2020	Changes to the SPC/product labelling/package leaflet following an Article 35 referral.
•	29 October 2019	Renewal - UK as CMS.
•	27 June 2019	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.
•	19 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.
•	09 July 2018	Addition of a manufacturer of the active substance.
•	06 July 2018	Change in RMS from UK to NL
•	24 October 2017	Changes to the SPC/product labelling/package leaflet

		following an Article 35 referral.
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