Veterinary Medicines Directorate

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Post Authorisation Assessments

Floxabactin 150 mg Tablets for Dogs

Vm 19994/3003

01 April 2025	Correction of the tablet description as the tablet is produced with a cross-shaped break line on one side. One-off alignment of the product information with version 9.0* of the QRD templates.
28 January 2025	Change in the manufacturing process of the finished product.
14 November 2024	Change in the quantitative composition of the immediate packaging.
27 June 2024	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance.
07 December 2023	Change in the specification limits of the finished product. Change in the specification limits of the finished product.
21 June 2022	Uniformity of dosage units is introduced to replace the currently registered method.
14 May 2021	Updates to product information.
30 March 2021	Submission of a new Ph. Eur. certificate of suitability for an active substance.
02 September 2019	Introduction of a new pharmacovigilance system.
25 April 2019	-Changes to the labelling, or the package leaflet, which are not connected with the SPC. -Change in distributor from: Bimeda Ltd, Broomhill Road,Tallaght, Dublin 24, Ireland to Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS, United Kingdom.
07 April 2016	Replacement of a site of batch release.
07 April 2016	Renewal – UK as CMS
26 February 2015	Submission of a new Ph. Eur. Certificate of Suitability.
07 December 2011	To assess the mock-ups prior to marketing.
22 September 2011	To change the distributor from Le Vet B.V to Bimeda.
01 August 2011	Addition of a manufacturing site and batch release site
5 April 2011	Change in the address of the Marketing Authorisation Holder.