Veterinary Medicines Directorate

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Post Authorisation Assessments

Floxabactin 150 mg Tablets for Dogs

Vm 19994/3003

•	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.