



Post Authorisation Assessments

Flimabend 100 mg/g Suspension for Use in Drinking Water for Chickens and Pigs Vm 01656/5064

•	08 March 2024	One-off alignment of the product information with version 9.0.
•	18 July 2023	Minor changes to an approved test procedure for the finished product.
•	11 April 2023	Deletion of a non-significant specification parameter of the finished product.
•	13 March 2020	Changes to the labelling and/or package leaflet.
•	23 April 2019	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	10 November 2017	Renewal – UK as CMS.
•	26 October 2017	Change in contact details for local representative.
•	30 March 2017	Approval of minor changes to the 750g pack size.
•	24 August 2016	Submission of an updated Ph. Eur. certificate of suitability.
•	24 August 2016	Addition of a new container for the finished product. Addition of new pack size. Addition of in use stability for PP containers with LDPE lid. Addition of in use shelf life: Shelf life after first opening the container: 6 months
•	14 October 2015	Changes to SPC & labelling due to new clinical data.
•	20 May 2015	To add the UK local representative information to the package leaflet.
•	18 February 2015	To change the shelf-life of the finished product from 2 years to 3 years.
•	22 November 2013	Variation to introduce an additional manufacturer for batch release.
•	14 October 2014	To confirm that appropriate target animal studies have been conducted