Veterinary Medicines Directorate

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Post Authorisation Assessments

Frusemide 40 mg Tablets

Vm 10434/4059

•	21 October 2022	Deletion of an alternative manufacturer / batch release site.
•	12 July 2022	Editorial changes to parts 2A and 2B of the dossier.
•	29 June 2022	Updated certificate of suitability for an already approved manufacturer of an active substance.
•	24 June 2022	Deletion of a manufacturer of the active substance.
•	22 June 2022	Deletion of an active substance manufacturer.
•	29 March 2022	Decrease in batch size range of the finished product.
•	29 March 2022	Addition of a site where batch control/testing takes place.
•	03 March 2022	Change(s) in the SPC, Labelling or Package Leaflet intended to implement the outcome of a PSUR.
•	23 July 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
•	11 October 2017	Changes to the labelling and package leaflet
•	06 September 2017	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer
•	29 September 2016	Change in the address of the Marketing Authorisation Holder.
•	18 September 2013	Change in test procedure performed on the finished product
•	27 August 2013	Change of specification of the finished product
•	19 April 2012	Change to immediate packaging of the finished product
•	19 November 2008	Minor change in the manufacturing process of the active substance
•	25 September 2008	Change of MAH
•	06 August 2008	Renewal
•	21 May 2008	Change to legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	26 February 2008	Change in test procedure of the finished product Change of shelf life from 5 years to 4 years