Veterinary Medicines Directorate

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Post Authorisation Assessments

Frusedale 40 mg Oral Tablets

Vm 10434/4033

•	20 October 2022	Deletion of an alternative manufacturer/ batch release site.
•	12 July 2022	Editorial changes to parts 2A and 2B of the dossier.
•	22 June 2022	Updated certificate of suitability for an already approved manufacturer of an active substance.
•	22 June 2022	Deletion of an active substance manufacturer.
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•	29 March 2022	Addition of a site where batch control/testing takes place.
•	29 March 2022	Decrease in batch size range of the finished product.
•	03 March 2022	Change(s) in the SPC, Labelling or Package Leaflet intended to implement the outcome of a PSUR.
•	08 August 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.
•	27 September 2017	Changes to the labelling and package leaflet
•	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 to specification of the finished product
•	19 April 2012	Change to immediate packaging
•	15 December 2010	Change of distributor
•	20 November 2008	Minor change in the manufacturing process of the active substance
•	12 March 2008	Renewal
•	26 February 2008	Change to test procedure performed on the finished product Change of shelf life of the finished product from 5 years to 4 years
•	16 August 2007	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	10 May 2007	Change of MAH
•	24 March 2004	Renewal
•	24 August 1999	Addition of a manufacturing and assembly site of the dosage form
•	07 June 1999	Change to manufacturer of the active substance Change of manufacturing site of assembly of the dosage

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