Veterinary Medicines Directorate

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Post Authorisation Assessments

Willcain Solution for Injection

Vm 36408/4014

•	June 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	18 August 2021	Change of Marketing Authorisation Holder from Dechra Ltd. to Alfasan Nederland B.V.
•	27 March 2020	Addition of a site where batch control/testing takes place.
•	12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
•	31 May 2018	Submission of a new Ph. Eur. certificate of Suitability for an active substance from a new manufacturer.
•	07 December 2017	Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	12 October 2017	Changes to the labelling and package leaflet.
•	29 September 2016	Change in the address of the Marketing Authorisation Holder.
•	05 December 2012	Variation to make a change in the manufacturing process of the finished product and to change the batch size of the finished product.
•	26 January 2011	Variation to change the distributor.
•	17 March 2010	Variation to change the name of the active substance manufacturer.
•	23 February 2010	Submission of an updated European Pharmacopoeia Certificate of Suitability for an already approved active substance manufacturer.
•	04 November 2008	Renewal.
•	11 June 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from PML to POM-VPS.
•	23 April 2008	Submission of an updated European Pharmacopoeia Certificate of Suitability for an already approved active substance manufacturer.
•	27 March 2008	Variation to change the Marketing Authorisation Holder.
•	21 July 2005	Variation to update the SPC.
•	30 March 2005	Renewal.
•	13 December 2001	Update Licence Particulars.
•	20 January 2000	Renewal.
•	17 November 1998	Change to the shelf-life of the finished product.
•	31 May 1995	Change to the formulation of the finished product.