Veterinary Medicines Directorate

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Post Authorisation Assessments

Procapen Injector 3g Intramammary Suspension for Cattle

Vm 24745/4023

•	18 June 2024	Change of distributor address from Cougar Lane, Naul, Co. Dublin, Ireland to Block 3, Unit 9, CityNorth Business Campus, Stamullen, Co. Meath, K32 D990, Ireland.
•	12 July 2022	Update to the ASMF.
•	24 September 2021	Change in the invented name of the veterinary medicinal product from Depocilline LC 3g intramammary suspension for cattle to Procapen Injector 3g Intramammary Suspension for Cattle in Germany.
•	05 November 2019	Changes to the labelling and package leaflet.
•	17 April 2019	Addition of a site where batch control takes place
•	01 June 2018	Renewal – UK as CMS.
•	01 May 2018	Change in the invented name of the veterinary medicinal product in Germany from Procapen Injector 3g Intramammary Suspension for Cattle to Depocilline LC 3g Intramammary Suspension for Cattle.
•	07 June 2017	Submission of an updated Ph. Eur. certificate of suitability for an already approved manufacturer.
•	02 May 2017	The introduction of a new manufacturer using an active substance master file.
•	24 February 2016	Additional site where batch control of the finished product takes place (Dr.E. Graub AG, Switzerland) Additional Secondary packaging site (animedica Herstellungs GmbH) Additional Secondary packaging site (Dr.E. Graub AG, Switzerland) Increase in the batch size (from 100 - 250 litres to 100 - 500 litres Dr. E. Gräub AG. only.) Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product (Alternative method for sterilisation of the carrier solution at Dr. E. Gräub AG. only.) Additional manufacturing site of the finished product (Dr.E. Graub AG, Switzerland)
•	02 December 2015	Additional manufacturer responsible for batch release.
•	04 June 2015	Harmonisation of the SPC and product literature.
•	13 March 2015	Changes to the test procedures for the finished product. Updates to the finished product specification. Change in the specification parameters/limits of the immediate packaging of the finished product.
•	11 March 2015	Addition of a specification parameter for the active

		substance. Submission of an updated Ph. Eur. Certificate of Suitability.