Veterinary Medicines Directorate

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Post Authorisation Assessments

Dolorex 10 mg/ml Solution for Injection for Horse, Dog and Cat

Vm 01708/3041

•	25 July 2024	Substantial changes in the updated version of an ASMF.
•	14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
•	13 November 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
•	15 August 2017	Deletion of manufacturing site for an active substance
•	01 December 2016	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	27 November 2014	Update of the pharmacovigilance system as described in the DDPS.
•	11 March 2013	To increase the batch size of active substance or intermediate by up to 10-fold and to make minor changes to a test procedure used in the manufacturing process of the active substance.
•	30 October 2012	Deletion of filling volume from the end of shelf life specification.
•	22 October 2012	Changes to the DDPS following assessment of the same DDPS in relation to another medicinal product of the same MAH.
•	22 August 2012	Reduction in the shelf life of the finished product as packaged for sale from 5 to 3 years.
•	23 November 2011	To submit an updated document for the active ingredient.
•	07 November 2011	Renewal – UK as CMS
•	10 March 2011	To change the name of the medicinal product in Spain only to: Butorvet 10 mg/ml solution for injection for horse, dog and cat.
•	17 December 2008	To add cats as a new target species
•	09 August 2007	To change the process of terminal sterilisation.