Veterinary Medicines Directorate

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Post Authorisation Assessments

Hexasol LA Solution for Injection for Cattle

Vm 02000/4152

•	22 June 2024	To introduce an additional immediate packaging of the finished product.
•	29 September 2023	Change in the specification parameter limits of the finished product.
•	16 June 2023	Minor change to an approved test procedure for the finished product.
•	20 March 2023	Update to Section 4.5, 5.2 and corresponding sections in PL
•	28 October 2022	Change in distributor details from Norbrook Laboratories (GB) Ltd, 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX, United Kingdom to Norbrook Laboratories Limited, Carnbane Industrial Estate, Newry, Co Down, BT35 6QQ, Northern Ireland.
•	25 August 2022	Deletion of a manufacturing site for an active substance.
•	05 January 2022	Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance.
•	28 September 2021	Minor changes to an approved test procedure of the finished product.
•	25 March 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	25 September 2020	Changes in the SPC, labelling and/or package leaflet - based on the VMD assessment report to change wordings in section 4.6 of the SPC and sections 6 and 12 of the product leaflet.
•	23 January 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance.
•	18 November 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	30 July 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	26 June 2019	Change of specification of a former non Pharmacopoeial excipient to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State. Change of specification of a former non Pharmacopoeial excipient to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State.

•	19 March 2019	Deletion of manufacturing site for an active substance Replacement of a manufacturing site of the finished product Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer
•	08 February 2019	Decrease in batch size range of the finished product.
•	18 January 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	06 December 2018	Change in test procedure to reflect compliance with the Ph. Eur. and remove reference to outdated internal test methods and test method numbers. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Deletion of a non-significant specification parameter of the finished product. Decrease in batch size range of the finished product.
•	02 July 2018	Change to part of the (primary) packaging material not in contact with the finished product formulation. Replacement of a supplier of packaging components or devices. Deletion of a supplier of packaging components or devices.
•	08 May 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	13 January 2015	Submission of a new or updated Ph. Eur. certificate of suitability.
•	10 November 2014	Changes to an existing pharmacovigilance system as described in the DDPS
•	21 February 2013	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	15 February 2012	Change of address of the distributor
•	19 December 2011	Submission of an updated Ph. Eur. Certificate of Suitability for the active substance
•	09 February 2011	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance
•	21 August 2008	Addition of 250ml and 500ml pack sizes
•	27 February 2008	Changes to the SPC and Product Literature to bring in line with new legislation
•	07 February 2007	Change of legal category from POM to POM-V
•	13 January 2006	Renewal
•	23 November 2005	Addition of a manufacturing site of assembly
•	24 February 2005	Change of in-use shelf life from 24 hours to 28 days
•	18 May 2001	Change to manufacturer of the active substance Change of formulation