Veterinary Medicines Directorate

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Post Authorisation Assessments

Ultrapen LA 30% Suspension for Injection

Vm 02000/4133

•	18 June 2024	To update the SPC and product literature as a result of EMA/V/A/145 – Referral for Procaine Benzylpenicillin.
•	07 March 2023	Deletion of - one of the authorised bulk or final containers of the finished product that does not lead to the complete deletion of a strength or pharmaceutical form. Addition of a supplier of packaging components or devices.
•	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.
•	06 July 2021	Deletion of a non-significant in-process test applied during the manufacture of the finished product.
•	27 May 2021	Deletion of a non-significant specification parameter of an excipient.
•	14 December 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	02 December 2020	Addition of a manufacturer of the active substance.
•	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.
•	27 June 2018	Change of specification of a former non Pharmacopoeial excipient to comply with the Ph.Eur.
•	21 March 2018	Change to part of the packaging material not in contact with the finished product formulation.
•	21 March 2018	Minor changes to an approved test procedure of the finished product. Update of the test procedure to comply with the updated general Ph. Eur monograph. Addition of a new specification parameter to the specification with its corresponding test method of the finished product.
•	02 March 2016	Submission of an updated certificate of suitability.
•	05 August 2015	Update in test procedure for finished product.
•	05 November 2013	Changes to packaging and change to shelf life.
•	04 July 2012	Additional supplier of the active substance.

•	21 March 2012	Change in distributor.
•	20 January 2009	Additional supplier of the active substance.
•	13 March 2008	Changes to the SPC and product literature to bring them into line with new legislation.
•	07 February 2007	Change of legal category from POM to POM-V.
•	13 June 2006	Renewal.
•	23 November 2005	Addition of a site of secondary assembly.
•	30 April 2004	Renewal.
•	19 April 2004	Change to milk withdrawal period for cattle, change to meat withdrawal period for pigs, change to meat withdrawal period for cattle.
•	23 February 2004	Change to withdrawal period for cattle.
•	26 March 1998	Change in product name.