Veterinary Medicines Directorate

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Post Authorisation Assessments

Colvasone 0.2% w/v Solution for Injection

Vm 02000/4009

•	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 March 2022	Changes in the SPC, Labelling or Package Leaflet intended to implement the outcome of a procedure concerning PSUR.
•	13 August 2021	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	28 July 2021	Increase in batch size of the finished product. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions.
•	12 March 2020	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.
•	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.
•	02 December 2009	Increase of withdrawal period for cattle milk from 72 hours to 84 hours
•	17 December 2008	Changes to the SPC and Product Literature to bring in line with new legislation
•	04 November 2008	Renewal

•	15 February 2007	Change of legal category from POM to POM-V
•	12 October 2005	Addition of a site of assembly
•	25 November 2004	Addition of a manufacturer of the active substance
•	11 November 2004	Changes to the SPC to bring in line with new legislation
•	23 April 2004	Renewal
•	11 June 1999	Renewal
•	10 September 1998	Change of manufacturing site of dosage form
•	28 May 1998	Additional presentation