Veterinary Medicines Directorate

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Post Authorisation Assessments

Tectomec 0.08% mg/ml Oral Solution Drench for Sheep

Vm 02000/4198

•	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.
•	18 August 2022	Deletion of a non-significant specification parameter for a raw material.
•	12 August 2022	Deletion of a non-significant specification parameter for a raw material.
•	02 August 2022	Deletion of certificates of suitability for an active substance.
•	06 July 2022	Change in dimensions of polyethylene back pack. Change in dimensions of polyethylene back pack. Addition of tamper evident cap.
•	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.
•	13 April 2018	Change in the invented name of the veterinary medicinal product from Premadex 0.8 mg/ml Oral Solution Drench for Sheep to Tectomec 0.8 mg/ml Oral Solution Drench for Sheep. Removal of distributor details.
•	27 July 2015	Submission of an updated certificate of suitability from an already approved manufacturer.
•	19 November 2014	Change in the invented name of the medicinal product, from ‘Vectin 0.08% w/v Oral Solution Sheep Wormer’ to ‘Premadex 0.8 mg/ml Oral Solution Drench for Sheep’.
•	30 October 2014	Change of distributor details.
•	05 December 2013	Submission of updated European Pharmacopoeia Certificates of Suitability for already approved active substance manufacturers.
•	15 June 2010	Addition of a statement to the product literature and section 4.9 of the SPC.
•	11 December 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	07 March 2007	Variation to change the legal category from PML to POM-VPS.
•	10 January 2007	Renewal.

•	15 November 2005	Addition of a site of assembly.
•	19 May 2005	Variation to extend the shelf life of the finished product.
•	15 April 2005	Variation to change the address of the distributor.
•	30 April 2004	Change of product name.
•	09 March 2004	Change of distributor name and address.
•	24 June 2003	Addition of a manufacturer and assembler of dosage form.