



Post Authorisation Assessments

Tectomec 5 mg/ml Pour on Solution

Vm 02000/4394

•	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.
•	21 November 2018	Change in the specification parameters and limits of an excipient.
•	02 August 2018	Change in shape or dimensions of the container or closure (immediate packaging)
•	17 April 2018	Change in the invented name of the veterinary medicinal product from Premadex 5.0mg/ml Pour On Solution to Tectomec 5.0mg/ml Pour On Solution. Change in distributor details. Downland Marketing Limited, 15 Victoria Place, Carlisle CA1 1EW Removed.
•	18 August 2016	Changes to wording on SPC plus removing prescriptive dosing instructions.
•	26 April 2016	Change in a test procedure for the finished product.
•	28 July 2015	Submission of an updated Ph. Eur. certificate of suitability from an already approved manufacturer.
•	08 July 2015	Change to the invented name of the veterinary medicinal product from "Depidex Pour-On Solution 0.5% w/v" to 'Premadex 5 mg/ml Pour on Solution'. Changes to section 5.2 on the SPC.
•	08 January 2015	Change of distributor.
•	11 November 2014	Change to the MAH.
•	02 November 2011	Approval of unseen mock ups.
•	30 September 2008	Change of legal category from PML to POM-VPS. Changes to the SPC and Product Literature to bring in line with new legislation.
•	07 December 2007	Change of address of the MAH.
•	23 October 2007	Renewal.
•	09 August 2000	Change of address of the MAH.