



Post Authorisation Assessments

Tectomec 5 mg/ml Pour on Solution

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| • | 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. |