



Post Authorisation Assessments

Ivermectin Pour-on Solution for Cattle 5 mg/ml Virbac Vm 05653/4149

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| • | 17 July 2024 | Change in the dimensions of the immediate packaging. |
| • | 12 June 2020 | Submission of a new Ph. Eur. certificate of suitability for an excipient from a new manufacturer |
| • | 14 January 2020 | Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS. |
| • | 17 July 2019 | Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter). |
| • | 18 December 2018 | Minor change to an approved test procedure for an excipient. Increase in batch size (including batch size range) of the finished product. Change in manufacturing process of the finished product |
| • | 23 December 2016 | Change in shape or dimensions of the container or closure for non-sterile medicinal products. Change in shape or dimensions of the container or closure for non-sterile medicinal products. Change in shape or dimensions of the container or closure for non-sterile medicinal products. Change in shape or dimensions of the container or closure for non-sterile medicinal products. |
| • | 02 September 2015 | Submission of a new certificate of suitability. |
| • | 30 April 2015 | Change in product name from Premadex Pour-On Solution for Cattle 5 mg/ml to Ivermectin Pour-On Solution 5 mg/ml Virbac |
| • | 11 July 2013 | Change in Distributor details |
| • | 10 July 2013 | Renewal. |
| • | 03 January 2013 | To update a Ph. Eur. Certificate of suitability from an already approved manufacturer. |
| • | 19 September 2012 | To add an additional manufacturer of an excipient. |
| • | 07 July 2010 | To add an additional site for manufacturer/assembler of dosage form. |
| • | 23 June 2010 | Variation to add an additional manufacturer responsible for batch release. |