



Post Authorisation Assessments

Diatrim 200 mg/ml + 40 mg/ml solution for injection for cattle, pigs, dogs and cats Vm 16849/5011

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| • | 18 May 2024 | Change in the SPC, Labelling or Packaging Leaflet to implement the safety warnings triggered by a referral on the excipient "N-methyl pyrrolidone". Addition of a 250 ml glass vial with a new additional stopper for this pack size. Introduction of a new pack size of 250 ml of the finished product. One-off alignment of the product information with version 9.0* of the QRD templates. |
| • | 03 July 2023 | New certificate of suitability from an already approved manufacturer. Replacement certificate of suitability from a new manufacturer. |
| • | 22 December 2022 | New certificate of suitability from an already approved manufacturer. Replacement certificate of suitability from a new manufacture. |
| • | 14 June 2022 | Unlimited Renewal |
| • | 24 January 2019 | Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. |
| • | 30 August 2018 | Change in RMS from UK to NL. |
| • | 15 May 2018 | Addition of a manufacturer of the active substance. |