Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS Telephone +44 (0)1932 336911

Post Authorisation Assessments

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

Vm 16849/3011

•	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.