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

Post Authorisation Assessments

Normazole 5 mg/ml Oral Solution for Cats Vm 02000/4400

	23 January 2024	Introduction of a summary of the PSMF or changes
•	20 January 2024	to the summary of the PSMF not already covered
		elsewhere in this Annex (NI)
	14 December 2022	Change in dimensions of the container or closure
•		(immediate packaging) of a non-sterile finished
		product.
•	04 July 2022	Change in distributor details from Norbrook
		Laboratories (GB) Ltd, 1 Saxon Way East, Oakley
		Hay Industrial Estate, Corby, Northamptonshire,
		NN18 9EX, United Kingdom to Independent Vetcare
		Ltd., The Chocolate Factory, Keynsham, Bristol, BS31 2AU.
•	24 May 2022	Change of local representative.
•	23 July 2021	Renewal – UK as CMS.
•	01 October 2020	Replacement of measuring device with CE markings
		which is not an integrated part of the primary
	0000	packaging.
•	08 January 2020	Minor changes to an approved test procedure of the finished product.
		Minor changes to an approved test procedure of the
		finished product.
•	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
•	26 June 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	27 February 2019	Change in RMS from UK to IE.
•	17 January 2019	Repeat Use application to add one new member state.