

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

Post Authorisation Assessments

Noroclox DC Xtra 600mg Intramammary Suspension Vm 02000/4126

•	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.
•	06 December 2018	Change in the specification parameters and limits for an excipient from USNF to manufacturer's specification.
•	27 July 2018	Changes to the labelling and package leaflet. Update distributor details on the QRD text.
•	01 May 2014	Addition of a manufacturer of an active substance.
•	11 June 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	14 May 2008	Variation to decrease the milk withdrawal period.
•	20 February 2007	Variation to transfer the legal category from POM to POM-V.
•	09 February 2006	Renewal.
•	21 July 2004	Variation to increase a withdrawal period.
•	21 July 2004	Renewal.
•	12 November 2001	Change of Distributor.
•	23 March 2001	Harmonisation of SPC.