



## Post Authorisation Assessments

### Chanazine 2% Solution for Injection Vm 08749/5063

11 September 2025	Change in legal entity of MA holder from Chanelle Animal Health Ltd, 7 Rodney Street, Liverpool, L1 9HZ, United Kingdom to Chanelle Pharmaceuticals Manufacturing Ltd, Loughrea, Co Galway, H62 FH90, Ireland.
10 October 2024	Change to comply with pharmacopoeia.
01 August 2022	Substantial changes in the updated version of the ASMF.
29 August 2019	Increase in batch size of the active substance used in the manufacturing process of the active substance. Tightening of specification limits of a related substance used in the manufacturing process of the active substance. Minor change to the restricted part of an Active Substance Master File. Change in the manufacturer of a starting material used in the manufacturing process of the active.
11 June 2018	Change in the specification limits of the finished product.
05 August 2015	Minor change in the manufacturing process of the active substance.
24 February 2014	Change in the manufacturing process of the active, change in test procedure for the active and change to the retest period of the active substance.
03 October 2012	Update of Active Substance Master File (ASMF)
06 April 2011	Addition of a new manufacturing site responsible for batch control
17 February 2011	Addition of a new site for manufacture and primary assembly
11 November 2009	Update of SPC and Product Literature safety warnings
30 January 2008	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
18 May 2006	Change in test procedure performed on the finished product
04 May 2006	Renewal
15 November 2001	Renewal
11 May 2000	Removal of milk withdrawal period Addition of contraindication for animals producing milk for human consumption

12 March 1998	Change of manufacturer of the active substance
03 September 1996	Renewal
20 June 1996	Change of shelf life
30 May 1996	Change of manufacturing site of the dosage form
24 May 1996	Change of operator warnings Addition of target species