



Post Authorisation Assessments

Chanazine 2% Solution for Injection

•	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