Veterinary Medicines Directorate

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Post Authorisation Assessments

Amoxinsol 50% w/w Powder for Oral Solution

Vm 08007/4019

•	25 March 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	18 August 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	17 December 2019	Change in test procedure to reflect compliance with the Ph. Eur. and remove reference to outdated internal test methods and test method numbers.
•	28 August 2018	Submission of a new Ph. Eur. certificate of suitability for an active substance excipient from a new manufacturer. Deletion of a non-significant specification parameter of the finished product.
•	23 May 2018	Deletion of a non-significant parameter of an active substance use in the manufacturing process of the active substance.
•	02 May 2018	Change in the address of the marketing authorisation holder from Vetoquinol UK Limited, Vetoquinol House, Great Slade, Buckingham Industrial Park, Buckingham, MK18 1PA to Vetoquinol UK Limited, Steadings Barn, Pury Hill Business park, Nr. Alderton, Towcester, Northamptonshire, NN12 7LS.
•	20 October 2016	Submission of a new certificate of suitability. Submission of an updated certificate of suitability.
•	19 September 2016	Change in batch size of the finished product.
•	10 May 2013	Significant changes to the SPC.
•	14 December 2012	Submission of two updated Ph. Eur. Certificates of Suitability for two already approved active substance manufacturers.
•	30 November 2012	Change to part of the primary packaging
•	27 June 2011	Increase in shelf life from 30mins after addition to liquid feed to 4 hours after addition to liquid feed.
•	14 July 2010	Addition of a method of administration of the product.
•	01 March 2010	Submission of a new Ph. Eur. Certificate of Suitability for an already approved active substance manufacturer.
•	07 May 2009	Addition of a site for batch release.
•	15 January 2009	Change in withdrawal period in chickens from 2 days to 24 hours.
•	14 February 2008	Variation to bring the SPC and labels in line with the new legislation and to transfer the legal category from POM to POM-V.
•	07 September 2007	Harmonisation of the SPC.

•	07 September 2007	Renewal.
•	03 February 2006	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance manufacturer.
•	23 November 2005	Change to batch release arrangements and quality control testing of finished product.
•	07 September 2005	Change to a manufacturing site.
•	10 June 2005	Change to MA holder address.
•	22 October 2004	Change to the finished product specification.
•	06 August 2004	Change to the name of a manufacturer.
•	30 July 2004	Addition of a site for finished product testing.
•	30 December 2003	Increase in withdrawal period for ducks, chickens and pigs.
•	12 December 2003	Renewal.
•	29 August 2003	Addition of a manufacturing site of the finished product.
•	30 September 2002	Change of manufacturer of the finished product.
•	02 January 2002	Addition of manufacturer of the active substance.
•	27 October 1997	Change in packaging.
•	22 November 1996	Renewal.
•	29 July 1996	Change in name of MA holder from Univet Ltd to Vetoquinol.
•	02 May 1995	Change to manufacturer of active substance.