Veterinary Medicines Directorate

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Post Authorisation Assessments

Amoxinsol 100% w/w Powder for Oral Solution

Vm 08007/4068

•	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.
•	23 May 2018	Deletion of a non-significant parameter of an active substance use in the manufacturing process of the active substance.
•	09 May 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	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.
•	15 May 2017	Submission of a new Ph. Eur. certificate of suitability for an active substance manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	03 June 2013	Submission of a new Ph. Eur. Certificate of Suitability for an already approved manufacturer of the active substance.
•	20 December 2012	Change of daily dosing and indications in poultry.
•	14 December 2012	Submission of an updated Ph. Eur. Certificate of Suitability for an already approved manufacturer of the active substance.
•	09 July 2012	Deletion of three sites for manufacture of the active substance, as well as submission of an updated Ph. Eur. Certificate of Suitability for an already approved active substance manufacturer and submission of a new Ph. Eur. Certificate of Suitability for a new manufacturer of the active substance.
•	01 March 2010	Submission of a new/updated Ph. Eur. Certificate of Suitability for an active substance
•	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.
•	29 February 2008	Removal of pigs as a target species.

•	29 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.
•	25 April 2006	Change of site of batch release.
•	15 March 2006	Renewal.
•	20 May 2005	Addition of a 200g pack size.
•	11 November 2004	Removal of manufacturer.
•	10 September 2004	Change in address of MAH.
•	27 May 2004	Change the test site for the finished product.
•	30 December 2003	Increase in withdrawal periods for chickens, ducks and pigs.
•	12 December 2003	Renewal and addition of a manufacturer of the dosage form.
•	18 December 2001	Change of manufacturer of active substance.
•	24 April 1997	Change in outer packaging.
•	17 January 1997	Change in formulation.