Veterinary Medicines Directorate

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Post Authorisation Assessments

Dolethal 200 mg/ml Solution for Injection

Vm 08007/4034

•	18 November 2022	Change(s) in the SPC, labelling or package leaflet 4.5 ad 12.
•	10 October 2022	Minor change to the manufacturing process.
•	28 February 2022	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	08 June 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	14 February 2019	Extension of a re-test period of the active substance.
•	15 October 2018	Deletion of manufacturing site for an active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. 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.
•	17 November 2011	Addition of a manufacturing site for the active substance
•	14 February 2008	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	28 December 2007	Change in packaging component
•	06 December 2006	Renewal
•	24 August 2004	Change of manufacturer for the assembly of the dosage form
•	18 August 2004	Change of address of the MAH
•	22 April 2004	Replacement of a manufacturer of the active substance
•	31 January 2003	Renewal
•	09 October 1997	Renewal
•	26 November 1996	Change of manufacturer of the active substance
•	19 June 1996	Change of name and address of MAH

•	02 April 1996	Change of shelf life