Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Xylapan 20 mg Solution for Injection

Vm 08007/5051

30 July 2024	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance.
13 March 2023	Addition of a new in-process test and limits applied during the manufacture of the finished product.
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.
26 February 2018	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer
20 April 2016	Submission of an updated certificate of suitability.
08 August 2012	Changes to the manufacturing process for the active substance.
28 March 2012	Reduction in the shelf life after first opening the immediate packaging from 28 days to 12 days.
07 December 2011	Variation to decrease the withdrawal period in cows and horses.
07 March 2011	Submission of a new Ph. Eur certificate of suitability for a new manufacturer of the active substance.
26 November 2009	Changes made to the SPC and product literature.
07 May 2009	Addition of a manufacturer of the finished product responsible for batch release.
23 January 2008	Changes to bring the SPC and product literature in line with new legislation and to change the legal category from POM to POM-V.
25 May 2007	Variation to replace the manufacturer of the finished product.
12 June 2006	Renewal.
12 October 2005	To change the milk withdrawal periods for cattle from not for use in cattle producing to milk for human consumption to a milk withdrawal period of 24 hours.
07 July 2005	Change of address for the manufacturer of the finished product responsible for batch release.
19 August 2004	Change of address for the Marketing Authorisation Holder (MAH).
30 December 2003	Variation to replace the active substance manufacturer.
31 January 2003	Changes to the specification for the active substance and changes to the release specification for the finished

	product.
07 November 2002	Minor changes to the manufacturing process for the product.
30 August 2002	Change of importer.
27 December 2001	Change of MAH name and address from Chassot (UK) Limited to Vetoquinol (UK) Ltd.
26 April 2000	Change to the milk withdrawal period for cattle from 48 hours to a contraindication.