Veterinary Medicines Directorate

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

Post Authorisation Assessments

Xeden 50 mg Tablet for Dogs

•	06 October 2021	Change in the SPC, labelling or package leaflet due to new data.
•	23 May 2019	Replacement of a site where batch control/testing takes place
•	05 April 2019	Change in the invented name of the veterinary medicinal product from Xeden to Xeden Vet in DK and NO.
•	22 November 2018	Replacement of a manufacturer responsible for batch release of the finished product. Deletion of a packaging site.
•	04 September 2018	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.
•	15 May 2018	Addition of a new specification parameter to the specification with its corresponding test method of an excipient. Deletion of a non-significant specification parameter of an excipient. Change in the specification limits of an excipient.
•	19 September 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	24 February 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	10 November 2016	Change in name / address of a manufacturer of the finished product. Change in name / address of a manufacturer of the finished product. Change in name / address of a manufacturer of the finished product.
•	29 September 2016	Approval of mock-ups due to change of design/layout.
•	29 June 2016	Introduction of a new pharmacovigilance system

		which has been assessed by the relevant national competent authority/EMA for another product of the same MAH.
•	14 June 2016	Change of MAH, from Sogeval to Ceva Animal Health Ltd and Change of Distributor to Ceva Animal Health Ltd.
•	11 January 2016	Changes to reduce the text on the outer carton for all three strengths of finished product.
•	06 August 2015	Submission of an updated certificate of suitability
•	24 September 2014	Repeat Use Comms.
•	25 April 2014	Submission of a new Ph. Eur. Certificate of Suitability for an already approved manufacturer of the active substance.
•	30 August 2013	Renewal.
•	27 August 2012	Addition of a batch size for the finished product.
•	01 October 2010	Change in the shelf-life of the finished product.
•	17 May 2010	To replace the site for primary packaging and add a supplementary site for secondary packaging.
•	23 March 2010	To add a new manufacturing site for all of the manufacturing process.