Veterinary Medicines Directorate

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Post Authorisation Assessments

Pracetam 10% Premix for Medicated Feeding Stuff for Pigs

Vm 15052/5035

•	23 August 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	23 June 2023	Deletion of a manufacturing site. Deletion of a manufacturing site for a finished product, packaging site and a batch release site. Deletion of a Ph. Eur. CEP for an active substance. Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance. Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
•	11 October 2022	Change in the address of the MAH from Unit 3 Anglo Office Park, White Lion Road Amersham, Buckinghamshire HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire HP10 0HH, United Kingdom.
•	08 July 2022	To change the batch size of the finished product at the additional manufacturing site in Italy. Addition of a new manufacturing site responsible for batch release and batch testing. Addition of a new manufacturing site responsible for the primary packaging of the finished product. Addition of a new manufacturing site responsible for the secondary packaging of the finished product. Addition of a new manufacturing site responsible of all manufacturing operations of the finished product.
•	30 March 2020	Change in control of excipients in the finished product. Addition to a test procedure for an excipient.
•	11 June 2019	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. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	23 May 2019	Replacement of a site where batch control/testing takes place
•	18 October 2018	Replacement of a manufacturer responsible batch release of the finished product.

•	16 July 2018	Change in specification parameter of an excipient
•	19 June 2018	Deletion of a non-significant specification parameter of the immediate packaging of the finished product.
•	18 December 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance manufacturer. Introduction of a re-test period of the active substance. Submission of a new Ph. Eur. certificate of suitability for an active manufacturer.
•	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.
•	19 July 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance manufacturer.
•	01 December 2016	Deletion of a manufacturing site and packaging site for the finished product.
•	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.
•	06 October 2016	Approval of mock-ups following 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.
•	19 April 2016	Deletion of 3 certificates of suitability. Submission of 3 certificates of suitability. Widening of specification for paracetamol particle size.
•	13 April 2016	Replacement* / addition* of a manufacturing site of the finished product
•	30 October 2013	Addition of a site of manufacturer of finished product (including primary and secondary packaging) and addition of a batch size.
•	29 August 2011	Change in the specification parameters/limits of an excipient and change in the specification parameters/limits of the finished product.
•	15 June 2011	Addition of a manufacturer of the actie substance supported by an EDQM certificate of suitability.
•	16 March 2011	Change of distributor.
•	23 April 2010	Renewal.
•	15 May 2007	Amendment to indications.
•	15 July 2006	Extension of shelf-life of the product as packaged for sale.