Veterinary Medicines Directorate

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Post Authorisation Assessments

Synuclav Palatable Tablets 500 mg for Dogs

Vm 02000/5015

•	May 2024	New CEP submitted for the manufacture of an active substance.
•	28 April 2024	Minor changes to the method of analysis for Potentiated Penicillin 500mg Tablets. Minor change in the test procedure for determination of the Total Aerobic Microbial Count, the Total Combined Yeast and Mould Count and an Absence of Escherichia coli in 1 gram for the finished product.
•	21 December 2023	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
•	25 August 2023	Deletion of a non-significant in-process test of the finished product. (GB)
•	15 February 2022	Deletion of a non-significant specification parameter of an excipient.
•	10 December 2019	Addition of a secondary packaging site of the finished product. 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.
•	30 July 2019	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.
•	03 June 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	11 January 2019	Change in the RMS from UK to ES.
•	04 January 2019	Update of the test procedure to comply with the updated general Ph. Eur monograph. Changes to a test procedure for the finished product.
•	30 August 2018	Changes to the labelling.
•	21 May 2018	Change in distributor details. From MiGroup, 12b Progress Way, Mid-Suffolk Business Park Eye, IP23 7HU, United Kingdom to MiGroup, CVS House, Owen Road, Diss, Norfolk, IP22 4ER, United Kingdom.
•	31 March 2016	Submission of new or updated Ph. Eur. certificates of suitability Deletion of Ph. Eur. certificates of suitability

•	10 September 2015	Change in the invented name of the medicinal product, from 'Clavapet' to 'Synuclav' in the UK only.
•	28 November 2014	Update to the DDPS.
•	07 November 2014	Change in the invented name of the medicinal product, from 'Combisyn' to 'Clavapet' in the UK only.
•	06 November 2014	Change to the name and address of the distributor on the package leaflet, and remove reference to the distributor on the carton and label.
•	19 September 2014	Change to the distributor address.
•	07 March 2013	Submission of updated Ph. Eur. Certificates of Suitability from already approved active ingredient manufacturers. Deletion of an active ingredient manufacturing site.
•	01 September 2011	Renewal – UK as RMS
•	09 August 2010	Repeat use -To add Iceland as a CMS.
•	23 October 2008	To include an additional manufacturer of the active ingredient, Potassium Clavulanate.