Veterinary Medicines Directorate

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

Post Authorisation Assessments

Synuclav 50 mg Tablets for Dogs and Cats

Vm 02000/5011

•	May 2024	New CEP submitted for the manufacture of an active substance.
•	25 April 2024	Minor change to the method of analysis for Potentiated Penicillin 50 mg Tablets. Minor change to the 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.
•	27 September 2023	Change in the shelf-life or storage conditions of the finished product.
•	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.
•	29 November 2019	Minor change in the manufacturing process of an immediate release solid oral dosage form. Qualitative / quantitative changes to the excipients.
•	03 June 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	14 January 2019	Change in 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.
•	23 March 2016	Submission of a new or updated Ph. Eur. certificate of suitability Submission of a new or updated Ph. Eur. certificate of suitability Submission of a new or updated Ph. Eur. certificate of suitability Deletion of a Ph. Eur. certificate of suitability Deletion of a Ph. Eur. certificate of suitability

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•	10 September 2015	Change in product name.
•	28 November 2014	Update to the DDPS.
•	06 November 2014	Change in product name.
•	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.
•	03 January 2014	Submission of European Pharmacopoeia Certificates of Suitability.
•	24 November 2011	Changes (Safety/Efficacy) to human and veterinary medicinal products.
•	27 April 2011	Deletion of a manufacturing site.
•	09 August 2010	Repeat use – To add Iceland as a CMS.
•	11 June 2009	Submission of a new/updated European Pharmacopoeia Certificates of Suitability.
•	25 April 2008	Change in composition of the immediate packaging.
•	09 April 2008	Change shelf life of finished product as packaged for sale.
•	17 April 2007	New/updated Ph. Eur Certificates of Suitability.
•	24 January 2007	Species addition, non-food.
•	30 September 2005	Change shelf life of finished product as packaged for sale.
•	27 June 2003	Additional pack type.