Veterinary Medicines Directorate

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# Post Authorisation Assessments

## Synuclav Suspension for Injection

Vm 02000/4226

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| • | 15 January 2020 | Replacement of a supplier of packaging components or devices. |
| • | 14 January 2020 | Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product. |
| • | 30 July 2019 | Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.<br>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. |
| • | 08 February 2019 | Minor changes to an approved test procedure of the finished product. |
| • | 30 January 2019 | Change in RMS from UK to ES. |
| • | 16 January 2019 | Introduction of a new site of manufacture. |
| • | 04 September 2018 | Replacement of a secondary packaging site of the finished product. |
| • | 07 August 2018 | Change in the invented name of the veterinary medicinal product in France from Noroclav Injectable to Clavobay Suspension Injectable. |
| • | 01 August 2018 | Change of specification of a former non Pharmacopoeial active substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State.<br>Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. |
| • | 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. |
| • | 11 April 2016 | Deletion of a manufacturing site of the active substance.<br>Submission of an updated certificate of suitability.<br>Submission of an updated certificate of suitability. |
| • | 07 October 2015 | Change of the invented name of the medicinal product in the UK, from ‘Clavapet’ to ‘Synuclav’. |

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| • | 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. |
| • | 03 January 2014 | Submission of an updated European Pharmacopoeia Certificate of Suitability for an already approved active substance manufacturer. |
| • | 17 August 2011 | Variation to add dog as a target species. |
| • | 09 August 2010 | Repeat Use Marketing Authorisation. Iceland added as CMS. |
| • | 22 September 2009 | Renewal procedure – UK as RMS. |
| • | 11 March 2009 | New/updated Ph. Eur Certificate of Suitability for active/active component from approved manufacturer.<br>Deletion of a manufacturing site. |
| • | 27 February 2008 | New/updated Ph. Eur Certificate of Suitability for active/active component TSE susceptible species. |
| • | 27 February 2008 | New/updated Ph. Eur Certificate of Suitability for active/active component TSE susceptible species. |
| • | 19 March 2007 | Lateral transfer of legal category. |
| • | 06 February 2006 | Change of name of the veterinary medicinal product in France only. |
| • | 13 May 2003 | Withdrawal period. |