Veterinary Medicines Directorate

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Post Authorisation Assessments

Kelaprofen 100 mg/ml Solution for Injection for Cattle, Horses and Pigs

Vm 06126/5000

•	12 October 2022	Change in the name of MAH from Kela N.V to Kela – Kempisch Laboratorium – Kela Laboratoria NV.
•	16 December 2021	Changes to the SPC and Package leaflet to implement the outcome of a PSUR.
•	25 June 2021	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
•	26 March 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product.
•	02 July 2020	Repeat Use application to add 3 new member states.
•	21 October 2019	Change in distributor details from ANUPCO Limited, Crockatt Road, Lady Lane Industrial Estate, Hadleigh, Suffolk, IP7 6RD, United Kingdom to ANUPCO Limited, Office 39, Lodge House, Lodge Park, Lodge Lane, Langham, Colchester, Essex, CO4 5NE, United Kingdom.
•	27 June 2019	Change in the specification limits of the finished product.
•	25 April 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	11 September 2018	Deletion of manufacturing site for an active substance 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 Changes to a test procedure for the finished product.
•	08 December 2016	Renewal - UK as CMS
•	21 March 2016	Submission of a new or updated Ph. Eur. certificate of suitability.
•	15 September 2014	Submission of new Ph. Eur. Certificates of Suitability.
•	21 May 2014	Repeat Use Comm.
•	26 March 2014	Change of Distributor.
•	27 November 2013	Change in the invented name of the product in Poland only.
•	09 September 2013	Change in batch size of the finished product
•	01 March 2013	Submission of an updated Ph. Eur. certificate of

		suitability for an already approved manufacturer.