Veterinary Medicines Directorate

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Post Authorisation Assessments

Florfenikel 300 mg/ml Solution for Injection for Cattle and Pigs

Vm 06126/4001

10 February 2025	Approval of mock ups.
04 July 2024	Addition of wording to advise the veterinary medicinal product should not enter water courses as florfenicol may be dangerous for fish, terrestrial plants, cyanobacteria and groundwater organism.
22 June 2024	Addition of a new in-process test and limits applied during the manufacture of the finished product. (GB)
13 October 2023	Amendments to relevant sections of the SPC following the endorsement by the European Commission of the CVMP Opinion on the Article 83 referral regarding VMPs containing N-methyl pyrrolidone (NMP) as an excipient.
14 October 2022	Change in the name of MAH from Kela N.V to Kela – Kempisch Laboratorium – Kela Laboratoria NV.
22 December 2020	Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product.
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.
16 September 2019	Increase in the shelf-life of the finished product as packaged for sale, from 24 to 36 months.
17 June 2019	Deletion of manufacturing site for an active substance Extension of a re-test period of the active substance. Change in manufacturer of a starting material used in the manufacturing process of the active substance. Change in the manufacturing process of the active substance.
25 April 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS
09 October 2018	Change in the RMS from UK to BE
11 January 2017	Renewal - UK as RMS.
22 June 2016	Addition of a site of manufacture.
14 April 2015	Addition of a target animal species.
10 March 2015	Change of distributor.