Veterinary Medicines Directorate

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Post Authorisation Assessments

Animeloxan 20mg/ml Solution for Injection for Cattle, Pigs and Horses

Vm 24745/4015

•	21 September 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. The outcome agreed at EU level should also be applied to all impacted GB and UK-wide licences.
•	02 August 2021	Increase in batch size (from 500 L to 500 L - 2000 L) of the finished product.
•	16 July 2021	Submission of a new certificate of suitability for an active substance.
•	11 May 2020	Addition of a manufacturer responsible for batch release not including batch control/testing. Addition of a manufacturing site of the finished product.
•	17 December 2019	Changes to the labelling and/or package leaflet.
•	28 August 2019	Changes to the SPC.
•	24 April 2018	Deletion of a manufacturing site for an active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	06 December 2017	Increase in the shelf-life of the finished product as packaged for sale, from 2 years to 3 years.
•	24 May 2017	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
•	20 April 2017	Renewal – UK as RMS
•	23 March 2017	Change in address of manufacturer of the finished product. Deletion of a manufacturing site. Replacement of a manufacturer for secondary packaging.
•	19 April 2016	Deletion of a manufacturing site for the finished product, and primary and secondary packaging.
•	30 March 2016	Submission of an updated Certificate of Suitability
•	24 June 2015	Addition of a site for batch control/testing for the finished product. Addition of a site for batch release for the finished product. Deletion of an active substance manufacturer. Addition of two sites for secondary packaging for the finished product. Addition of a manufacturing site for part of the manufacturing process of the finished product. Addition of a manufacturing site for the finished product.
•	07 November 2014	Change to the wording in section 4.6. of the SPC and

		section 6. of the package leaflet.
•	10 July 2014	Submission of a new Ph. Eur. Certificate of Suitability for a new manufacturer of the active substance.
•	07 December 2012	To change the QPPV.