



Post Authorisation Assessments

Premadex 10 mg/ml Solution for Injection Vm 13277/4017

•	02 June 2023	Change of MAH address from Eco Animal Health Ltd, 78 Coombe Road, New Malden, Surrey, KT3 4QS United Kingdom to Eco Animal Health Ltd, The Grange, 100 High Street, London, N14 6BN United Kingdom.
•	28 April 2023	Change in immediate packaging of the finished product - Addition of a new container. Change in pack size of the finished product.
•	06 August 2021	Change in the invented name of the veterinary medicinal product from Qualimec 10 mg/ml Solution for Injection to Premadex 10 mg/ml Solution for Injection.
•	28 April 2021	Deletion of manufacturing site for an active substance. Deletion of manufacturing site for a finished product.
•	09 March 2020	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	6 November 2019	Reduction of the shelf life of the finished product as packaged for sale from 36 months to 24 months.
•	14 March 2018	Tightening of specification limits of the finished product.
•	25 October 2016	Change in the QPPV and/or QPPV contact details and/or back-up procedure. Change in the QPPV and/or QPPV contact details and/or back-up procedure.
•	29 May 2012	Change in the distributor
•	26 October 2011	Change in immediate packaging of the finished product.
•	03 November 2010	Renewal – UK as CMS.
•	04 May 2010	To change the address of the distributor.
•	13 January 2010	To increase the withdrawal period for cattle (meat) from 42 days to 49 days.
•	02 October 2008	Manufacturer (active)
•	15 May 2008	New /updated Ph. Eur CofS for active/active components from manufacturer
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