Veterinary Medicines Directorate
Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the EMA website.

Kriptazen 0.5 mg/ml Oral Solution for Calves

Vm 05653/5012

•	May 2024	Change in the shape or dimensions of the container of a non-sterile finished product.
•	28 April 2024	Separating package leaflet to make it monolingual and GB only packaging.
•	23 January 2024	Approval of mock ups.
•	18 August 2023	Unlimited Renewal.
•	05 April 2023	Change in the specification limits of the finished product. Extension of the shelf life of the finished product as packaged for sale.
•	19 January 2022	Minor change in the manufacturing process of the finished product.
•	15 December 2021	Changes to the SPC and package leaflet to implement the outcome of assessment by the CVMP.
•	07 October 2021	Change in the manufacturer of a starting material used in the manufacturing process of the active. Change in the re-test period/storage period or storage conditions of the active substance.
•	05 August 2021	Change in immediate packaging of the finish product. Change in immediate packaging of the finish product.
•	26 May 2021	Addition of a new specification parameter to the specification with its corresponding test method of a measuring or administration device for veterinary medicinal products. Addition of a new specification parameter to the specification with its corresponding test method of a measuring or administration device for veterinary medicinal products. Change in specification parameters and/or limits of a measuring or administration device for veterinary medicinal products. Changes to a test procedure (including replacement) of a measuring or administration device for veterinary medicinal products.