



## Post Authorisation Assessments

### Ketodolor 100 mg/ml Solution for Injection for Horses, Cattle, Pigs Vm 41821/4004

•	22 November 2023	Change in the batch size of the finished product. Change in the holding time of the bulk product.
•	28 July 2022	Change in distributor details from Virbac Limited, Unit 16 Woolpit Business Park, Windmill Avenue, Bury St. Edmunds, Suffolk, IP30 9UP, United Kingdom to Dechra Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS, United Kingdom. Change in distributor.
•	02 March 2022	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	05 November 2019	Introduction of a new pharmacovigilance system.
•	25 March 2019	Change in RMS from UK to IE.
•	28 November 2018	Renewal – UK as RMS.
•	25 May 2017	Increase in the shelf-life of the finished product as packaged for sale, from 24 months to 36 months.
•	08 September 2016	Change of distributor details. Mock-ups agreed.
•	02 January 2015	Change to section 4.2 of the SPC and corresponding product literature.