



Post Authorisation Assessments

Equest Oral Gel 18.92mg/g Oral Gel for Horse and Ponies

Vm 42058/5142

•	26 May 2023	Changes in the composition (excipients) of the finished product.
•	26 May 2023	Change in name of the active substance or of an excipient. Change in name of the active substance or of an excipient.
•	26 May 2023	Change in name of the active substance or of an excipient. Change in name of the active substance or of an excipient.
•	10 January 2020	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
•	05 March 2019	Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products - Instructions for using dosing device updated.
•	07 November 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	14 February 2018	Changes to the SPC/product labelling/package leaflet following an Article 35 referral.
•	09 November 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	07 October 2016	Mock-ups approved.
•	05 June 2015	Change in the QPPV and/or QPPV contact details and/or back-up procedure
•	04 July 2014	Submission of an updated Ph. Eur. Certificate of Suitability.
•	30 October 2013	Changes to an existing pharmacovigilance system and change to the name of a manufacturer responsible for the finished product and batch release.
•	24 October 2013	Change to the name of the MAH in France only.
•	31 July 2013	Transfer of MA from Pfizer Ltd to Zoetis UK Limited and change of distributor.
•	20 March 2013	Change in pack size of the finished product. Change in specification parameters and/or limits of finished product. Change in the batch size of the finished product Change in test procedure for the finished product Change in supplier of packaging components

		Change in shape/dimensions of the container or closure system.
•	13 June 2012	Introduction of a new pharmacovigilance system
•	21 February 2012	Approval of a new presentation: a box with 20 syringes.
•	04 November 2011	Change in name/address of a manufacturer of the finished product.
•	02 September 2011	Submission of a new Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	16 June 2010	Change of MAH
•	09 February 2009	Change of specification of the active substance to comply with Ph. Eur.
•	29 February 2008	Change in composition of immediate packaging
•	26 September 2007	Renewal
•	27 February 2007	Change of colour scheme of primary packaging
•	18 July 2006	Change of legal category from PML to POM-VPS Updates to the Product Literature
•	21 April 2004	Change of dosing device (larger syringe)
•	04 July 2003	Renewal Addition of an efficacy claim
•	07 March 2003	Change of manufacturing process of the active substance
•	04 September 2001	Change of starting materials used in the manufacture of the active substance
•	16 May 2001	Addition of an efficacy claim
•	18 May 2000	Change of shelf life from 18 months to 24 months
•	23 December 1999	Addition of a manufacturing site of the active substance
•	22 November 1999	Change of size of sterile containers
•	04 August 1999	Change of shelf life