Veterinary Medicines Directorate

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Post Authorisation Assessments

Tribex 5% Oral Suspension for Sheep

Vm 11990/4033

•	04 May 2024	Submission of a new Ph. Eur. CEP from an already approved manufacturer for a non-sterile. (NI)
•	04 May 2024	Changes to the quality part of the dossier, deletion of a manufacturing site for an active substance. (NI)
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•	04 May 2024	Submission of a new Ph. Eur. CEP from an already approved manufacturer for a non-sterile. (GB)
•	04 May 2024	Changes to the quality part of the dossier, deletion of a manufacturing site for an active substance. (GB)
•	26 October 2021	To change the mock ups design for the product.
•	26 July 2018	Updates to the SPC and product literature following the outcome of a periodic safety update report.
•	27 April 2017	Addition of a manufacturer of the active substance
•	20 July 2016	Change in the specification parameters of the active substance.
•	19 June 2015	Addition of a new manufacturing site for the active ingredient.
•	29 July 2013	Variation to update a test procedure of a related substance of the active substance.
•	13 May 2013	Grouped variation concerning: the deletion of a non-significant in-process test used during manufacture of the finished product, the extension of the finished product shelf life, and the widening of shelf life specifications.
•	07 May 2013	Variation to update the SPC and Labelling following the outcome of a European Commission Decision Article 35 Referral for all Veterinary Medicinal Products containing active substances belonging to the class of Flukicides.
•	20 September 2012	Grouped variation concerning: the deletion of an active substance manufacturer, a change in the name of the active substance manufacturer, the addition of an active substance manufacturer, and a change in the melting point specification of an active substance.
•	08 June 2011	Implementation of an additional Warning statement on the SPC/Labelling.
•	23 November 2010	Addition of an active substance manufacturer.
•	08 August 2008	EU Renewal.
•	02 July 2004	Addition of a user warning.