



Post Authorisation Assessments

Tribex 10% Oral Suspension for Cattle Vm 11990/4034

•	18 October 2018	Change in the number of units in a pack outside the range of the currently approved pack sizes of the finished product. Change in the fill volume of the finished 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 specification parameters of the active substance.
•	25 June 2015	Changes to mock-ups.
•	19 June 2015	Addition of a new manufacturing site for the active ingredient.
•	09 April 2015	Changes to the milk withdrawal period.
•	26 September 2013	Variation to update the test procedure used in test methods for substances related to the active substance.
•	13 May 2013	Grouped variation to: delete a non-significant in-process test used during finished product manufacture, extend the shelf life of the finished product, widen the shelf life specifications for an excipient.
•	07 May 2013	Variation to update the SPC/Labelling for products related to cattle and sheep following a European Commission Decision Article 35 Referral.
•	20 September 2012	Grouped variation to: delete an active substance manufacturer, change the name of an active substance manufacturer, add a new active substance manufacturer, change of a melting point for a process used in the manufacture of the active substance.
•	23 November 2010	Addition of an active substance manufacturer.
•	14 July 2010	Variation to make changes/simple corrections to the product labelling.
•	08 August 2008	UK Renewal.
•	02 July 2004	Addition of a safety warning.
•	12 March 2004	Addition of a safety warning.