



Post Authorisation Assessments

Tribex 10% Oral Suspension for Cattle

Vm 11990/4034

13 December 2024	Editorial changes to labelling.
06 July 2024	Changes to the quality part of the dossier, deletion of a manufacturing site for an active substance. Changes to the quality part of the dossier, deletion of a manufacturing site for an active substance. (GB)
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.