



## Post Authorisation Assessments

### Tricalcert 5% Oral Suspension for Sheep Vm 11990/4051

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|---|-------------------|---|
| • | 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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| • | 13 March 2023     | Change in the distributor address from Downland Marketing Ltd, 15 Victoria Place, Carlisle, CA1 1EW to Downland Marketing Ltd, Warwick Mill Business Centre, Warwick Bridge, Carlisle, CA4 8RR.                               |
| • | 10 August 2020    | Change in the invented name of the veterinary medicinal product from Fascicur 5% Oral Suspension for Sheep to Tribex 5% Oral Suspension for Sheep in France only.   |
| • | 28 April 2017     | Addition of a manufacturer of the active substance  |
| • | 20 July 2016      | Change in the particle size specification of the active ingredient  |
| • | 16 June 2015      | Addition of a new manufacturing site for the active ingredient.   |
| • | 13 May 2013       | Grouped variation: Deletion of active substance assay at the top, middle and bottom of mixing vessel prior to mixing. Extension of shelf life of finished product from 18 months to 3 years.                                  |
| • | 20 September 2012 | Grouped variation: Change of name of active substance manufacturer. Deletion of a manufacturer of the active substance. Addition of an active substance manufacturer. Change in specification limits for an active substance. |
| • | 23 November 2010  | To add an additional supplier of the active substance   |
| • | 20 February 2009  | Renewal - UK as CMS   |