Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS Telephone +44 (0)1932 336911

Post Authorisation Assessments

Animec Super 10 mg/ml / 100 mg/ml Solution for Injection for Cattle Vm 11990/4054

Other changes to the active substance: - Substantial changes in the updated version of the ASMF or the active substance part of the dossier. Paper 2022 Increase in batch size (Up to 10-fold increase) of the active substance used in the manufacturing process of the active substance. Change in the manufacturing process of the active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. 22 September 2021 Repeat use application to add 6 member states. 13 March 2020 Change in the SPC, labelling or package leaflet to harmonise texts of CMSs. 04 April 2019 Repeat Use application to add 1 new member state 28 November 2018 Change of RMS from UK to PT. 24 July 2018 Addition of a secondary packaging site of the finished product. 17 July 2018 Deletion of manufacturing site for an active substance. Addition of a manufacturer of the active substance or addition of a manufacturer. 25 April 2017 Addition of a manufacturer. 08 February 2016 Submission of a Ph. Eur. certificate of suitability for the active substance manufacturer. 14 July 2015 Renewal procedure. 13 May 2015 Submission of an updated certificate of suitability. 13 September 2013 Change of product name from 'Animec Super Solution for Injection for Cattle' to 'Covertin Plus' in Italy only New - MRP 27 May 2010 To replace the batch release site.			
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