



Post Authorisation Assessments

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

•	03 February 2023	Other changes to the active substance: - Substantial changes in the updated version of the ASMF or the active substance part of the dossier.
•	29 April 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 manufacturer of a starting material / reagent/ intermediate used in the manufacturing process of the active substance.
•	22 April 2022	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 site of manufacture.
•	25 April 2017	Addition of a manufacturer of the active substance
•	10 November 2016	Submission of a Ph. Eur. certificate of suitability for the active substance manufacturer.
•	08 February 2016	Addition of a manufacturing site Change in the batch size
•	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
•	17 May 2011	New - MRP
•	27 May 2010	To replace the secondary assembly site.
•	27 May 2010	To replace the batch release site.