



Post Authorisation Assessments

Mycoflor, 300 mg/ml Solution for Injection for Cattle and Pigs

Vm 36967/3004

30 July 2025	Other changes to the active substance: - Substantial changes in the updated version of the ASMF.
30 July 2025	Other changes to the active substance: - Substantial changes in the updated version of the ASMF.
29 April 2025	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
06 July 2024	Changes to sections: SPC: 4.5 Special precautions for use 6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products Labelling (outer): 12. Special precautions for the disposal of unused products or waste materials, if any Package leaflet: 12. Special warnings 13. Special precautions for the disposal of unused products or waste materials, if any
08 April 2024	Incorporation of the changes required following the outcome of the referral for products including NMP as an excipient. (NI)
08 April 2024	Incorporation of the changes required following the outcome of the referral for products including NMP as an excipient. (GB)
13 July 2023	Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier: -Introduction of a manufacturer of the active substance supported by an ASMF.
31 March 2020	Updated Active Substance Master File.
26 June 2018	Change in the RMS from UK to IE.
09 May 2017	Addition of a manufacturer of the active substance or addition of a site of manufacture
08 December 2016	Renewal – UK as RMS
14 April 2015	Addition of a target animal species.