



Post Authorisation Assessments

Ecomectin 5 mg/ml Pour-on Solution for Cattle Vm 13277/4021

07 October 2025	Change to comply with Ph. Eur. (NI)
11 August 2025	Change to comply with Ph. Eur. (GB)
13 May 2025	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI only).
22 December 2024	Addition of a site of batch control. (NI only)
30 July 2024	Correction of a typographical error.
30 July 2024	Amendments to relevant sections of the SPC following the endorsement by the European Commission of the CVMP Opinion on the Article 83 referral regarding VMPs containing N-methyl pyrrolidone (NMP) as an excipient.
30 July 2024	Change(s) in the Summary of Product Characteristics (SPC), labelling or package leaflet intended to implement the outcome of a Union interest referral procedure according to Article 83 of Regulation (EU) 2019/6. Addition of NMP warnings subsequent to a referral process.
01 June 2023	Change of MAH address from Eco Animal Health Ltd, 78 Coombe Road, New Malden, Surrey, KT3 4QS United Kingdom to Eco Animal Health Ltd, The Grange, 100 High Street, London, N14 6BN United Kingdom.
15 February 2021	Addition of a site where batch control/testing takes place.
06 January 2021	Addition of a manufacturer responsible for batch release of the finished product. Deletion of manufacturing site for an active substance. Deletion of manufacturing site for a finished product.
15 April 2020	Change in the invented name of the veterinary medicinal product from Ecomectin 5 mg/ml Pour-on Solution for Cattle to Dophamec 5mg/ml Pour-on Solution for Cattle in Germany only.
09 March 2020	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
24 December 2019	Changes to the labelling and package leaflet.
10 May 2019	Minor change in the manufacturing process of the finished product. Change to a test procedure for the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
09 November 2018	Renewal – UK as CMS.

25 October 2016	Change in the QPPV and/or QPPV contact details and/or back-up procedure. Change in the QPPV and/or QPPV contact details and/or back-up procedure.
13 June 2014	To change the limits of the finished product. To reduce the shelf-life of the finished product to 24 months.
02 May 2012	Submission of updated mock-ups for approval.
17 November 2011	EU Renewal, UK as CMS.
21 August 2008	Harmonisation of mock-ups between the UK and IE.
15 August 2008	Addition of a manufacturer.
30 July 2008	Addition of a site responsible for batch release.
29 July 2008	Addition of a batch size of the finished product.