



Post Authorisation Assessments

Z-Itch 40 mg/ml Pour-on Solution Vm 56190/3000

26 February 2026	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Change in the pharmacovigilance system master file (PSMF) location.
09 December 2025	Change in distributor from Trilanco Ltd, Coronation Way, Mill Farm Sports Village, Wesham, Preston PR4 3JZ to Duggan Veterinary Supplies Ltd. Unit 9, Thurles Retail Park, Garryvicleheen, Thurles, Co. Tipperary, E41 E7K7, Ireland
20 June 2025	Submission of updated mock ups.
19 January 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
20 April 2023	One-off alignment of the product information with version 9.0 of the QRD template.
13 April 2023	Repeat use to add 1 new CMS
03 February 2023	Replacement of a microbiological testing site for the finished product.
21 December 2022	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
23 February 2022	Change in the name and address of the marketing authorisation holder in Northern Ireland from Floris Animal Health Ltd., Bath House 6-8, Bath Street, Bristol, BS1 6HL, United Kingdom to Floris Holding BV, Kempenlandstraat 33 / 35, 5262 GK Vught, The Netherlands.
22 October 2020	Repeat use: To add 3 new member states.
04 May 2020	Change of MAH from Floris Veterinaire Produkten BV, Kempenlandstraat 33 / 35, 5262 GK Vught, Netherlands to Floris Animal Health Ltd., Bath House 6-8, Bath Street, Bristol, BS1 6HL, United Kingdom.
18 December 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
02 August 2019	Variation to update the SPC and QRD text.
08 April 2019	RMS change from UK to IE.
08 April 2019	Repeat Use application to add 3 new member states.
14 August 2017	Replacement of a site where batch control/testing takes place.

15 February 2017	Change in Distributor address, from Trilanco Limited, Bracewell Avenue, Poulton Business Park, Poulton-le-Fylde, Lancashire FY6 8JF to Trilanco Limited, Coronation Way, Mill Farm Sports Village, Wesham, Preston PR4 3JZ.
08 September 2016	Verification of GMP compliance of the manufacturer of the active substance.
16 August 2016	Renewal – UK as RMS.