



Post Authorisation Assessments

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

•	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.