

## Post Authorisation Assessments

### Z-Itch 40 mg/ml Pour-on Solution Vm 56190/5000

23 March 2026	Addition of contact details for a local representative and reporting of adverse reactions- DUGV (UK) Ltd., Union House, 111 New Union Street, Coventry, CV1 2NT, United Kingdom Tel: +44 (0) 2476 100696, E-mail: pv@dugganvet.ie.
09 March 2026	Change of distributor from Trilanco Ltd, Coronation Way, Mill Farm Sports Village, Wesham, Preston PR4 3JZ to DUGV (UK) Ltd. Union House, 111 New Union Street, Coventry, CV1 2NT.
17 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.
14 November 2025	Alignment of the product information with version 9.0* of the QRD templates.
26 January 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance.
19 October 2023	Change in legal entity of MA holder from Floris Animal Health Limited, Bath House, 6-8 Bath Street, Bristol BS1 6HL to Floris Holding BV, Kempenlandstraat 33 / 35, 5262 GK Vught, The Netherlands.
10 August 2022	Change in name of a manufacturer of the finished product. Change in address of a manufacturer of the finished product. Addition of a quality control testing site for the finished product.
23 February 2022	Dealignment
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.