Veterinary Medicines Directorate

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Post Authorisation Assessments

Flectron Fly Ear Tags for Cattle 935 mg

Vm 42058/5164

05 October 2026	Change in the composition of the immediate packaging. Change in a finished product test procedure. Change in a finished product test procedure.
6 August 2026	Minor change to an approved finished product test procedure. Minor change to an approved active substance test procedure. Minor change to an approved active substance test procedure. Minor change to an approved active substance test procedure. Deletion of a non-significant specification parameter for an active substance. Tightening of a specification parameter for an active substance. Addition of a new specification parameter with test method.
24 October 2025	Alignment of the product information with version 3 of the GB QRD templates.
29 September 2025	Change in test procedure for the finished product: - Other changes. Change in the holding time of an intermediate.
09 September 2025	Change to comply with Ph. Eur. By removal of reference to an internal test reference and test method number. Change to comply with Ph. Eur. By removal of reference to an internal test reference and test method number. Deletion of an analytical test method for the intermediate product. Minor changes to an approved test method for the finished product.
24 April 2025	Change in the specification parameters and/or limits of the finished product.
14 November 2024	Change in legal entity of MA holder for UK(NI) from Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP to Zoetis Belgium S.A., 2nd Floor, Building 10, Cherrywood Business Park, Loughlinstown, Co. Dublin, Ireland.
09 February 2024	Replacement of an excipient with a comparable excipient with the same functional characteristics and at a similar level.
08 April 2021	Replacement of an excipient with a comparable excipient.
21 December 2020	Change in the Summary of Product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a Union referral procedure.
28 August 2020	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
24 June 2020	Replacement of a site where batch control/testing takes place. Addition of a manufacturer responsible for batch release of the

	finished product.
01 July 2019	Change in the manufacturer of the active where no Ph. Eur. Certificate of Suitability is part of the approved dossier. The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer.
12 September 2017	Replacement of an excipient with a comparable excipient.
30 July 2014	Change in the name of a manufacturer of the finished product Change of MAH from Pfizer Ltd to Zoetis UK Limited Approval of amended mock-ups Change of distributor
30 March 2011	Change of manufacturer of the active substance
16 March 2011	Change of manufacturer of the active substance
24 June 2010	Change of MAH
24 July 2008	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
10 December 2007	Renewal
10 September 2003	Renewal
08 November 2002	Addition of a manufacturer of the finished product
20 August 2002	Change to specification of the finished product
30 May 2002	Change of name of manufacturer of the finished product Change to test method performed on the finished product
19 April 2001	Renewal
30 March 2001	Change of manufacturer of the active substance Change of specification of the finished product
17 February 1999	Change to QC procedures