Veterinary Medicines Directorate

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Post Authorisation Assessments

Flectron Fly Ear Tags for Cattle 935 mg

Vm 42058/5164

•	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