Veterinary Medicines Directorate

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Post Authorisation Assessments

Frontline Spot on Cat 10% w/v Spot on Solution

Vm 08327/4133

•	08 June 2023	Change in the shelf-life or storage conditions of the finished product. Change in the specification parameters and/or limits of the finished product.
•	12 April 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	20 December 2021	Deletion of a specification parameter of the finished product.
•	15 July 2021	Change in the specification limits of the finished product.
•	17 March 2021	Changes in the qualitative and quantitative composition of the immediate packaging (pipette) of the finished product.
•	05 March 2021	Change in the number of units (pipettes) in a pack within the range of the currently approved pack sizes of the finished product. Change to part of the (primary) packaging material not in contact with the finished product formulation.
•	28 May 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	01 November 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Ltd, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
•	29 August 2018	Change in the address of the supplier used for the manufacture of the active substance. Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance. Change of specification(s) of a former non Pharmacopoeial active substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State.
•	11 January 2018	Minor change in the manufacturing process of the finished product.
•	07 December 2017	Changes to the labelling and package leaflet.
•	01 November 2016	Addition of a secondary packaging site of the finished product.
•	20 November 2015	Change in legal distribution category from NFA-VPS to AVM-GSL.

		Deletion of an indication from the SPC.
•	27 March 2014	Change in the manufacture of the finished product at a manufacturing and release site.
•	26 March 2014	Deletion of a manufacturing site.
•	01 July 2008	Change of name and address of the manufacturer of the active susbtance's head office
•	07 May 2008	Minor changes in the manufacture of the active substance
•	20 June 2007	Changes to the SPC and product Literature to bring in line with new legislation
•	17 May 2006	Renewal
•	05 April 2006	Change of legal category from POM to NFA-VPS
•	14 January 2005	Change to product label to include the species name 'cat'
•	06 August 2004	Update to safety sections of the SPC and Product Literature
•	11 June 2004	Change of shelf life from 24 months to 36 months
•	29 May 2003	Change to test methods performed on the active substance
•	22 November 2002	Renewal
•	07 November 2002	Addition of a manufacturing site for assembly of the finished product
•	27 September 2002	Change to specification of the active substance Change of manufacturer of the active substance
•	20 August 2002	Addition of indications for breeding, pregnant and lactating queens Additional contraindications
•	28 September 2001	Addition of new indication for use against lice Change to contraindications regarding bathing before and after treatment Updates to the SPC and Product Literature
•	11 January 2001	Change of manufacturing site for part of the manufacturing process of the active substance Change of specification of the active substance Change of manufacturing process of the active substance
•	11 July 2000	Addition of indication for product to be used as part of a treatment for Flea Allergy Dermatitis in Cats and Dogs
•	02 June 2000	Change of batch size Change of type of non-sterile containers
•	29 March 2000	Addition of indication 'for prevention and treatment of ticks'
•	30 November 1999	Change of specification of the finished product
•	29 November 1999	Additional presentation
•	08 September 1999	Addition of safety warnings contraindicating rabbits
•	10 August 1999	Update of licence particulars
•	04 February 1999	Change of shelf life from 12 to 24 months
•	10 November 1998	Additional presentations
•	06 March 1998	Change of MAH
•	03 March 1998	Change of size of sterile containers
•	24 January 1997	Additional presentation