



Post Authorisation Assessments

Frontline Spray 0.25% w/v Cutaneous Spray Solution

•	28 May 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	29 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.
•	23 July 2018	Deletion of a therapeutic indication.
•	13 March 2018	Change in the name and address of a manufacturer of the finished product including manufacturer responsible for batch release.
•	20 February 2018	Change of legal category from POM-V to NFA-VPS
•	27 July 2016	Assessment of mock-ups following a previous variation affecting shelf-life and storage conditions.
•	03 May 2016	Change storage conditions of the finished product. Change in the shelf-life of the finished product from 2 years to 3 years.
•	10 January 2013	Change of shape of the immediate packaging
•	01 July 2008	Change of name and address of the manufacturer and manufacturing site of the active substance
•	07 May 2008	Minor change to the manufacturing process of the active substance
•	20 June 2007	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	14 November 2005	Renewal
•	20 April 2005	Updates to the SPC and Product literature
•	13 November 2003	Change to test procedures performed on the active substance
•	30 September 2003	Incorporation of a dosing device into the immediate packaging
•	18 September 2003	Change to specification of the excipients

		Change to finished product specification
•	27 September 2002	Change of specification of the active substance Change of manufacturer of the active substance
•	28 September 2001	Addition of an indication against lice
•	25 January 2001	Minor change to manufacturing process of the active substance Change of manufacturing site for part of the manufacturing process of the active substance Change of specification of the active substance
•	11 July 2000	Change to indications to include the product as part of a Flea Allergy Dermatitis treatment plan
•	29 March 2000	Changes to indications to include prevention and treatment of ticks
•	10 February 2000	Renewal
•	23 August 1999	Changes to safety warnings
•	18 June 1998	Change of MAH
•	20 March 1997	Changes to safety warnings Changes to indications
•	10 January 1996	Change of manufacturer of the active substance Change to dosage particulars
•	16 June 1995	Change to safety warnings
•	07 March 1995	Minor change of manufacturing process of the active substance
•	15 February 1995	Minor change of manufacturing process of the active substance