Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Johnson's 4Fleas 57mg Tablets for Dogs

Vm 00879/4062

•	19 March 2024	Non-significant specification parameter for an excipient deleted.
•	25 May 2023	Change in test procedure for the finished product: - Other changes to a test procedure.
•	23 May 2023	Minor change to an approved test procedure for the finished product.
•	21 December 2021	Deletion of a non-significant parameter of an active substance. Deletion of a non-significant parameter of an active substance.
•	02 March 2021	Changes to a test procedure for the finished product.
•	22 October 2020	Change in the address of the Marketing Authorisation Holder from Elanco Europe Ltd, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom to Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	11 May 2020	Minor change in the manufacturing process of the finished product. Addition of new tests and limits applied during the manufacture of the finished product.
•	09 December 2019	Change in shape or dimensions of the container or closure (immediate packaging).
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	16 February 2017	To amend section 4.6 of the SPC and the related text in the product literature.
•	10 August 2016	Change in the name of a manufacturer of the finished product.
•	21 June 2016	Change in the legal entity from Novartis Animal Health UK Ltd to Elanco Europe Ltd.
•	02 June 2016	Deletion of a non-significant in-process test applied during the manufacture of the finished product. Change in the re-test period of the active substance.
•	12 June 2014	Change in test procedures and specification parameters of the finished product.
•	12 June 2014	Change in test procedures and change in specification parameter of an active substance.
•	13 November 2013	Changes in manufacture of a starting material used in the production of the active substance

•	06 July 2011	Change of specification for the finished product
•	15 June 2011	Change to the manufacturing process of the active substance
•	23 September 2009	Changes to Part II of the Dossier
•	10 July 2009	Batch control
•	20 February 2009	Renewal
•	28 January 2009	Change of shelf life specification for the finished product
•	28 August 2008	Change in test procedure performed on the finished product
•	05 August 2008	Batch control
•	16 July 2008	Increase of bulk holding time from 2 weeks to 3 months
•	29 April 2008	Change of legal category from GSL to AVM-GSL Changes to the SPC and Product Literature to bring in line with new legislation
•	29 January 2008	Change of address of the MAH and Distributor
•	23 January 2008	Change to storage instructions from 'Do not store above 25˚C' to 'Store Refrigerated'
•	05 April 2006	Change of manufacturer of the active substance
•	11 February 2005	Addition of a 3 tablet pack size
•	05 December 2003	Addition of a manufacturing site of assembly of the dosage form