



Post Authorisation Assessments

Johnson's 4Fleas 11.4 mg Tablets for Small Dogs and Puppies Vm 00879/4061

•	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 th June 2014	Change in test procedures and change in specification parameter of an active substance.
•	12 th June 2014	Change in test procedures and specification parameters of the finished product.
•	13 th November 2011	Registration of the synthetic route of manufacture of a starting material used to produce the active substance.

•	13 th November 2011	Addition of a supplier of a starting material used to produce the active substance.
•	6 th July 2011	Change in the specification of the active substance.
•	15 th June 2011	Changes in the manufacturing process of the active substance.
•	23 rd September 2009	Update to Part II of the dossier.
•	20 th February 2009	Renewal
•	28 th January 2009	Change in shelf life specifications of the finished product.
•	28 th August 2008	Change in the test procedure of the finished product.
•	16 th July 2008	Change in bulk holding time of finished product.
•	29 th April 2008	Change of legal category from GSL to AVM-GSL.
•	29 th April 2008	Changes to the SPC and product literature in line with new legislation.
•	29 th January 2008	Change in the address of the MAH.
•	24 th January 2008	Change in the storage conditions of the finished product.
•	5 th April 2006	Change in the manufacturer of the active substance.
•	4 th February 2005	Addition of a pack size of 3 tablets.
•	5 th December 2003	Additional of a site of secondary assembly.
•	5 th December 2003	Removal of an indication.
•	5 th December 2003	Change of product name from Johnson's 4Fleas Tablets for Small Dogs and Puppies, Cats and Kittens to Johnson's 4Fleas 11.4mg Tablets for small dogs and puppies.