



Post Authorisation Assessments

Johnson's 4Fleas 57mg Tablets for Dogs Vm 00879/5077

23 April 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance.
19 June 2024	Minor change to an approved test procedure for the finished product.
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