Veterinary Medicines Directorate

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

Post Authorisation Assessments

Johnson's 4Fleas 11.4 mg Tablets for Cats and Kittens

Vm 00879/4060

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.
12th June 2014	Change in test procedures and change in specification parameter of an active substance.

12th June 2014	Change in test procedures and specification parameters of the finished product.
13th November 2013	Registration of the synthetic route of manufacture of a starting material used to produce the active substance.
13th November 2013	Addition of a supplier of a starting a material used to product the active substance.
6th July 2011	Change in the specification of active substance.
15th June 2011	Change in the manufacturing process of the active substance.
15th June 2011	Change in the manufacturing process of the active substance.
15th June 2011	Change in the manufacturing process of the active substance.
23rd September 2009	Update to Part II of the dossier.
20th February 2009	Renewal
28th January 2009	Change in shelf life specifications of the finished product.
28th August 2008	Change in test procedure of the finished product.
16th July 2008	Change to bulk holding time.
29th April 2008	Change in legal category form GSL to AVM-GSL.
29th April 2008	Change to the SPC and product literature to bring in line with new legislation.
29th January 2008	Change in the MAH address.
24th January 2008	Change of storage conditions.
5th April 2006	Change in the manufacturer of the active substance.
4th February 2005	Addition of a pack size of 3 tablets.
5th December 2003	Removal of an indication.
5th December 2003	Change of product name from Johnson's 4Fleas 11.4mg Tablets for Cats and Kittens, Small Dogs and Puppies to Johnson's 4Fleas 11.4mg Tablets for Small Cats and Kittens.
5th December 2003	Addition of a site of secondary assembly of dosage form.