



Post Authorisation Assessments

Johnsons Fipronil 50 mg Spot-On Solution for Cats Vm 02000/4329

•	22 December 2023	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
•	14 December 2023	Change in dimensions of the container or closure (immediate packaging) of a non-sterile finished product. (NI) Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. (NI) Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. (NI)
•	31 July 2023	Change in dimensions of the container or closure of a non-sterile finished product. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible.
•	16 November 2021	Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product.
•	24 August 2021	Minor changes to an approved test procedure of the finished product.
•	06 January 2021	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.
•	30 July 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	31 July 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	28 June 2017	Renewal - UK as CMS.
•	19 June 2017	Addition of a secondary packaging site of the finished product.
•	21 December 2016	Change in the invented name of the veterinary medicinal product from Fleanil to Bolfo in Germany only.
•	29 August 2014	Changes to the DDPS.

•	16 July 2014	Addition of a manufacturer responsible for batch release.
•	26 June 2014	Addition of a site for secondary assembly.
•	24 June 2014	Change to the invented name of the product from 'Spot and Clear 50 mg Spot-on Solution for Cats' to 'Johnson's Fipronil 50 mg Spot-On Solution for Cats'.
•	03 June 2014	Change of distributor.
•	23 October 2013	Extension of shelf life of the product as packaged for sale from 2 years to 3 years.
•	02 August 2013	Change in the name of the medicinal product in Germany only from Pestigon 50 mg Spot-On Solution for Cats to Fleanil 50 mg Spot-On Solution for Cats.
•	12 April 2013	Addition of a new therapeutic indication.
•	21 February 2013	To change the legal category from NFA-VPS to AVM-GSL.
•	16 November 2012	To update the text on the outer and immediate packaging.
•	29 June 2012	Removal of an indication.