



Post Authorisation Assessments

Pets with Wilko Flea Drops 134 mg Spot-on Solution for Medium Dogs Vm 52797/4015

•	14 September 2022	Changes to the labelling or the package leaflet which are not connected with the summary of product characteristics.
•	30 August 2022	Change in the invented name of the veterinary medicinal product from Wilko Flea Drops 134 mg Spot-on Solution for Medium Dogs to Pets with Wilko Flea Drops 134 mg Spot-on Solution for Medium Dogs.
•	29 April 2021	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	29 May 2020	Change of MAH, from Bob Martin (UK), Wemberham Lane, Yatton, Somerset, BS49 4BS, United Kingdom to Pets Choice Limited, Brentwood House, Lower Philips Road, Whitebirk Industrial Estate, Blackburn, Lancashire, BB1 5UD, United Kingdom.
•	09 May 2018	Renewal - National
•	24 October 2017	Change to part of the (primary) packaging material not in contact with the finished product formulation. Change to more restrictive storage conditions of the active substance. Tightening of specification limits of an active substance used in the manufacturing process of the active substance.
•	23 June 2017	Deletion of a therapeutic indication. Change in distribution category to AVM-GSL
•	24 February 2017	Change in the invented name of the veterinary medicinal product from Fipracyl Spot On Solution 134 mg for Medium Dogs to Wilko Flea Drops 134 mg Spot-on Solution for Medium Dogs.
•	09 June 2016	Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance. Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Deletion of a manufacturing site (for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)).
•	05 March 2014	Approval of mock-ups.

•	31 May 2013	Changes to an existing pharmacovigilance system as described in the DDPS.
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