Veterinary Medicines Directorate

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Post Authorisation Assessments

Prevensa 40 mg + 10 mg Spot-on Solution for Small Dogs

Vm 00879/4149

•	19 December 2022	Extension of the re-test period of the active substance
•	03 March 2022	Removal of all references to Local Representative. Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
•	25 June 2021	Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance. Introduction of a re-test period of the active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	23 October 2020	Change of MAH from Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD to Elanco Europe Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	24 April 2020	Renewal – National.
•	18 September 2018	Change in distributor details from Bayer plc, Animal Health Division, Strawberry Hill, Newbury, Berkshire, RG14 1JA to Bayer plc, 400 South Oak Way, Green park, Reading, Berkshire, RG2 6AD.
•	29 August 2018	Change in the invented name of the veterinary medicinal product from Multi-parasite 40 mg + 10 mg Spot-on Solution for Small Dogs to Prevensa 40 mg + 10 mg Spot-on Solution for Small Dogs.
•	20 June 2018	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
•	27 July 2017	Change in the name of a manufacturer used in the manufacture of the active substance.
•	05 May 2017	Change in the address of the marketing authorisation holder from Bayer plc, Animal Health Division, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA to Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD.
•	01 September 2016	Changes to SPC and product literature following the assessment of the same change for the reference product.
•	24 May 2016	Changes to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH
•	17 May 2016	Addition of a new therapeutic indication for the treatment of cutaneous dirofilariosis (adult stages of Dirofilaria

		repens).
•	8 December 2015	Addition of a secondary packaging site.
•	25 August 2015	Change in test procedure for the finished product.
•	30 June 2015	Submission of an updated certificate of suitability.