



Post Authorisation Assessments

Prinovox 400 mg + 100 mg Spot-on Solution for Extra-Large Dogs Vm 00879/4157

•	21 February 2023	Change in the re-test period of the active substance.
•	13 February 2023	Change in the re-test period of the active substance.
•	09 February 2022	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
•	05 August 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.
•	23 June 2021	Renewal - UK as CMS.
•	08 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.
•	26 October 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
•	03 July 2018	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
•	23 April 2018	Change in RMS from UK to DE.
•	05 January 2018	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.
•	24 August 2017	Change in the name of a manufacturer used in the manufacture of the active substance.
•	15 June 2017	Change in the number of units (e.g. tablets*, ampoules*, etc.) in a pack outside the range of the currently approved pack sizes of the finished product.
•	16 May 2017	MRP (UK as RMS)
•	24 May 2016	Changes to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH
•	18 May 2016	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
•	25 August 2015	Change in test procedure for the finished product.
•	30 July 2015	Additional manufacturing site for secondary packaging.

•	30 June 2015	Submission of an updated certificate of suitability.
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