



Post Authorisation Assessments

Prinovox 100 mg + 25 mg Spot-on Solution for Medium Dogs Vm 00879/4153

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| 16 December 2025 | Submission of an updated Ph. Eur. CEP for an active substance. (NI) |
| 23 September 2025 | Submission of an updated Ph. Eur. CEP for an active substance. (GB) |
| 16 September 2025 | Update to the antiparasitic statements as per the EMA guideline. One-off alignment of the product information with version 9.1 of the QRD template. |
| 08 April 2025 | Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (GB). |
| 19 January 2025 | Submission of a new Ph. Eur. CEP from a new manufacturer for a non-sterile active substance. (NI) |
| 22 December 2024 | Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI) |
| 27 November 2024 | Submission of a new Ph. Eur. CEP from a new manufacturer for a non-sterile active substance. (GB) |
| 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. |
| 24 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. |

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| 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 | Addition of a manufacturing site for secondary packaging. |
| 30 June 2015 | Submission of an updated certificate of suitability. |