Veterinary Medicines Directorate

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# Post Authorisation Assessments

## MiPet Benazapet 2.5 mg Tablets for Cats and Dogs

Vm 00879/4000

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| • | 02 December 2021 | Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product.<br>Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product. |
| • | 01 December 2021 | Deletion of manufacturing site for an active substance. |
| • | 16 November 2021 | Change to part of the (primary) packaging material not in contact with the finished product formulation.<br>Change in the manufacturing process of the finished product.<br>Deletion of a non-significant in-process test applied during the manufacture of the finished product. |
| • | 08 October 2021 | Change to part of the (primary) packaging material not in contact with the finished product formulation.<br>Deletion of a non-significant specification parameter of the immediate packaging of the finished product.<br>Change in the specification parameters and/or limits of the immediate packaging of the finished product.<br>Change in the specification parameters and/or limits of the immediate packaging of the finished product.<br>Change in the specification parameters and/or limits of the immediate packaging of the finished product.<br>Change in the specification parameters and/or limits of the immediate packaging of the finished product.<br>Change in the specification parameters and/or limits of the immediate packaging of the finished product.<br>Change in the specification parameters and/or limits of the immediate packaging of the finished product. |
| • | 15 June 2021 | Change in the specification parameters and/or limits of the immediate packaging of the finished product.<br>Deletion of a non-significant specification parameter of the immediate packaging of the finished product.<br>Deletion of a non-significant specification parameter of the immediate packaging of the finished product.<br>Change in the specification parameters and/or limits of the immediate packaging of the finished product.<br>Change in the specification parameters and/or limits of the immediate packaging of the finished product.<br>Change in the specification parameters and/or limits of the immediate packaging of the finished product.<br>Change in the specification parameters and/or limits of the |

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| | | immediate packaging of the finished product.<br>Change in the specification parameters and/or limits of the immediate packaging of the finished product. |
| • | 25 March 2021 | Replacement to a test procedure for the finished product. |
| • | 04 February 2021 | Deletion of manufacturing site for a manufacturer responsible for batch release. |
| • | 12 January 2021 | Change in the address of the marketing authorisation holder from Elanco Europe Ltd, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL to Elanco Europe Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom. |
| • | 15 December 2020 | Renewal – National. |
| • | 30 July 2019 | Addition of a site where batch control/testing takes place. |
| • | 05 June 2019 | Change in the safety database of an existing pharmacovigilance system as described in the DDPS. |
| • | 28 December 2018 | Change in the name of a manufacturer used in the manufacture of the active substance. |
| • | 06 November 2018 | Tightening of specification limits of the finished product. |
| • | 04 April 2018 | Change in the address of a manufacturer of the active substance.<br>Change in the address of a manufacturer of the active substance.<br>Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. |
| • | 18 May 2017 | Change in the name of a manufacturer of the active substance |
| • | 07 March 2017 | Introduction of a new pharmacovigilance system. |
| • | 11 October 2016 | Addition of a test site for the finished product.<br>Addition of a test method for the active substance.<br>Addition of a test method for the intermediate.<br>Addition of a test method for the intermediate.<br>Addition of a site of manufacture for the active substance. |
| • | 10 August 2016 | Change in the name of a manufacturer of the finished product including manufacturer responsible for batch release. |
| • | 09 August 2016 | New test method for residual solvent benzene. |
| • | 26 November 2015 | Re-definition of a starting material and addition of a new manufacturer of a starting material. |