Veterinary Medicines Directorate

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Post Authorisation Assessments

MiPet Benazapet 20 mg Tablets for Dogs

Vm 00879/4001

•	12 June 2024	Additional adverse reactions added to product literature.
•	10 May 2023	Other changes.
•	01 December 2021	Deletion of manufacturing site for an active substance.
•	15 June 2021	Deletion of a non-significant specification parameter of the immediate packaging of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product. 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. Change in the specification parameters and/or limits of the immediate packaging of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product. 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.
•	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.
•	17 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.
•	04 April 2018	Change in the address of a manufacturer of the active substance. Change in the address of a manufacturer of the active substance.

		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. Addition of a test method for the active substance. Addition of a test method for the intermediate. Addition of a test method for the intermediate. 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.