Veterinary Medicines Directorate

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Post Authorisation Assessments

Banacep Vet 5 mg Film-Coated Tablet for Dogs and Cats
Benazepril Hydrochloride

Vm 20634/3004

•	28 February 2024	Addition of a secondary packaging site for the finished product.
•	14 August 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance. (GB)
•	28 July 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance, – starting material, reagent or intermediate used in the manufacturing process of the active substance, or – excipient.
•	12 July 2023	Addition of a secondary packaging site of a finished product.
•	30 March 2022	Decrease in batch size range of the finished product. Addition of a site where batch control/testing takes place. Addition of a site where batch control/testing takes place. Addition of a manufacturing site of the finished product. Addition of primary packaging site of the finished product. Addition of secondary packaging site of the finished product.
•	10 February 2022	Deletion of Ph. Eur. certificates of suitability for an active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance.
•	30 July 2021	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
•	11 October 2016	Change in the design of the blister packs.
•	20 April 2016	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	25 April 2014	Addition of an active substance manufacturer.
•	08 February 2013	Renewal procedure – France as RMS.
•	15 February 2012	Submission of a new or updated Ph. Eur. certificate of suitability.
•	12 January 2010	To add ‘cats’ as a new target species.
•	19 August 2008	Repeat Use Comm