



Post Authorisation Assessments

Banacep Vet 5 mg Film-Coated Tablet for Dogs and Cats Benazepril Hydrochloride Vm 20634/3004

20 April 2026	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. Change(s) in the name or address or contact details of a qualified person for pharmacovigilance.
30 September 2025	SRP application to add two new member states.
07 April 2025	Change of the Local Representative from Laboratorios Calier S.A., C. Barcelones 26 (Pla del Ramassa) 08520 Les Franqueses del Vallès, Spain. To Forte Healthcare Ltd, Block 3, Unit 9, CityNorth Business Campus, Stamullen, Co. Meath. K32 D990, Ireland, Contact phone number: +353 1 841 7666, Contact e-mail: pharmacovigilance@fortehealthcare.com .
22 June 2024	One-off alignment of the product information with version 9.0 of the QRD templates.
28 April 2024	Submission of an updated certificate of suitability.
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