



Post Authorisation Assessments

Prilben Vet 5 mg Film-Coated Tablet for Dogs and Cats Benazepril Hydrochloride Vm 20916/4042

•	06 March 2024	Change in legal entity of MA holder from Chemo Ibérica S.A., C/ Dulcinea S/N, Alcalá de Henares, 28805, Spain to CP-Pharma Handelsgesellschaft mbH, Ostlandring 13, 31303 Burgdorf, Germany.
•	05 March 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	19 May 2020	Replacement of a manufacturer responsible for batch release including batch control/testing. Replacement of a secondary packaging site of the finished product. Replacement of a primary packaging site of the finished product. Replacement of a manufacturing site of the finished product.
•	18 December 2019	Change in the address of the marketing authorisation holder from: Chemo Ibérica S.A., De Carles III 98, Planta 7 A, Barcelona, 08020, Spain, to: Chemo Ibérica S.A., C/ Dulcinea S/N, Alcalá de Henares, 28805, Spain.
•	08 March 2019	Introduction of a new pharmacovigilance system.
•	09 May 2018	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	21 December 2012	Renewal procedure.
•	29 June 2012	Replacement of primary and secondary packaging sites. Change to batch size of finished product, replacement of a manufacturing site responsible for batch release.
•	15 February 2012	Submission of a new or updated Ph. Eur. Certificate of Suitability.
•	17 August 2011	To change the distributor.
•	13 January 2010	To add 'cats' as a new target specie (to treat chronic renal insufficiency) and consequently change the product name to Prilben vet 5 mg film-coated tablet for dogs and cats benazepril hydrochloride.
•	13 October 2009	To change the distributor.
•	19 August 2008	Repeat Use Comm.