



Post Authorisation Assessments

Actikor 5 mg Film-coated Tablets for Dogs

•	06 November 2018	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	18 January 2017	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	22 December 2016	Renewal - UK as CMS.
•	15 June 2016	Submission of an updated Certificate of suitability.
•	19 August 2013	Minor change in the manufacturing process of an immediate release solid oral dosage form
•	26 October 2012	Minor changes to a test method for the finished product. Changes to in-process test limits for the finished product.
•	09 July 2012	Submission of a new Ph. Eur certificate of suitability.
•	29 September 2011	To change the shelf-life of the finished product as packaged for sale from 24 months to 3 years.
•	11 August 2011	Grouped variation to change the product name in all member states. The UK name changed from 'Benazepril Hydrochloride Accord 5 mg Film-coated Tablets for Dogs' to 'Actikor 5 mg Film-coated Tablets for Dogs'
•	11 August 2011	Grouped variation to add an additional site for batch release.
•	28 July 2011	To change the Marketing Authorisation Holder from Accord Healthcare Limited to Ecuphar NV, Belgium