



Post Authorisation Assessments

Benazecare Flavour 5 mg Tablets for Dogs and Cats

•	30 September 2021	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
•	23 October 2018	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	16 April 2018	Change of RMS from UK to IE.
•	08 August 2017	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	01 May 2014	Submission of a new Ph. Eur. Certificate of Suitability for a new manufacturer of the active substance.
•	11 July 2013	Submission of a new Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer. Change to comply with an update of a relevant monograph of Ph. Eur. Or national pharmacopeia of a member state. Change in the name of the address of the MAH.
•	31 May 2012	Update Summary of Product Characteristics and product literature following an Article 34 referral.
•	10 February 2012	Deletion of a manufacturing site.
•	11 January 2012	Renewal - UK as RMS.
•	23 September 2009	To re-formulate the product by adding a new flavouring and remove the film coating on the tablet.
•	26 November 2008	Variation to update DMF for ScinoPharm
•	26 September 2008	Variation to add cats as a target species.

