



Post Authorisation Assessments

Amodip 1.25 mg Chewable Tablets for Cats

•	01 July 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	07 May 2021	Changes to the labelling and package leaflet.
•	23 November 2020	Change in the invented name of the veterinary medicinal product in DK, EE, FI, LT, NO, and SE.
•	02 November 2020	Deletion of manufacturing site for an active substance.
•	30 March 2020	Renewal - UK as CMS.
•	01 July 2019	Replacement of a site where batch control/testing takes place.
•	22 March 2019	Change of RMS from UK to FR.
•	22 March 2019	Repeat Use procedure to add 6 CMS
•	24 May 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	03 October 2017	Change in the invented name of the veterinary medicinal product from Amlodipine 1.25 mg Ceva chewable tablets for cats to Amodip 1.25 mg chewable tablets for cats, in the UK only.
•	19 September 2017	Change in 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.
•	19 September 2017	Change in the name and/or address of the MAH in Spain only.
•	01 March 2017	Change in shelf-life of the finished product from 30 months to 3 years.
•	26 January 2017	Change of MAH from Orion Corporation to Ceva Animal Health Ltd.
•	15 November 2016	Submission of an updated Ph. Eur certificate of suitability for an active substance from an already approved manufacturer.
•	31 August 2016	Introduction of a new pharmacovigilance system which has been assessed by the relevant national competent authority/EMA for another product of the same MAH.
•	16 August 2016	Change in the name of the manufacturing site, primary & secondary packaging site and batch control site. Replacement of a manufacturer responsible for batch release. Deletion of a manufacturing site, primary & secondary packaging site and batch control site.

•	08 March 2016	Change in the invented name of the veterinary medicinal product from 'Vivelin' to 'Amlodipine'.
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