



## Post Authorisation Assessments

### Amodip 1.25 mg Chewable Tablets for Cats

Vm 14966/3021

19 January 2026	Submission of updated mock ups.
26 September 2025	Change of legal entity of the Marketing Authorisation Holder from Ceva Animal Health Ltd, Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH United Kingdom to Ceva Sante Animale, 8 rue de Logrono, 33500 Libourne, France.
27 June 2025	Change in the re-test period/storage period of the active substance: - Introduction of a re-test period supported by real time data. Submission of an updated Ph. Eur. certificate of suitability for an active substance.
20 May 2025	Minor change to an approved test procedure for an excipient. (NI).
20 May 2025	Minor change to an approved test procedure for an excipient. (GB).
04 April 2025	One-off alignment of the product information with version 9.0* of the QRD template.
22 June 2024	Change in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (GB)
13 September 2022	Change of MAH address from: Unit 3 Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
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'.