Veterinary Medicines Directorate
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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the EMA website.

Reconcile 16 mg Chewable Tablets for Dogs

Vm 54790/5001

•	22 March 2024	Alternative container added for the finished product.
•	19 October 2023	Minor changes to an approved test procedure for active substance for the finished product. Submission of a new Ph. Eur. CEP from a new manufacturer (replacement or addition) for a non-sterile: – active substance.
•	26 April 2023	Additional site for batch testing of the finished product. Minor changes to an approved test procedure for the finished product.
•	19 April 2023	Replacement of a manufacturer of the finished product responsible for importation. Replacement of a manufacturer of the finished product responsible for batch release.
•	25 January 2023	Introduction of a re-test period for the active substance.
•	17 January 2023	New certificate of suitability from a new manufacturer.
•	04 March 2022	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	November 2021	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product for solid pharmaceutical forms. Minor changes to an approved test procedure of the finished product.
•	14 October 2021	Introduction of a new pharmacovigilance system.
•	13 July 2021	Deletion of manufacturing site for an active substance where batch control takes place.
•	27 May 2021	Change of MAH, from Pegasus Laboratories Ireland Limited, 10 McCurtain Hill, Clonakilty, County Cork, P85 K230 Ireland to FORTE Healthcare ltd, 13 Ayr Road, Prestwick, South Ayrshire, KA9 1SX UK