Veterinary Medicines Directorate
Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

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

Reconcile 8 mg Chewable Tablets for Dogs

Vm 27819/5002

28 July 2026	Change in the test procedure for the finished product.
08 March 2026	Minor changes to an approved test procedure for the finished product. Change in the specification parameters or limits of the finished product to describe more accurately the appearance of the product.
08 March 2026	Replacement of a single excipient with a comparable excipient with the same functional characteristics and at a similar level. Addition of a scored line on one side of the tablet. Extension of the shelf life of the finished product after first opening supported by real time data, from 30 days to 60 days.
12 December 2025	Minor change to an approved test procedure for the finished product.
04 November 2025	Change in legal entity of MA holder from Forte Healthcare Ltd, 13 Ayr Road, Prestwick, South Ayrshire, KA9 1SX, United Kingdom to Forte Healthcare Limited, Cougar Lane, Hazardstown, Naul, Co. Dublin, K32 FH74, Ireland.
09 October 2025	Change in the shelf-life or storage conditions of the finished product: - Extension of the shelf life of the finished product. One-off alignment of the product information with version 3 (V3) of the QRD template.
08 April 2025	Change to batch control arrangements (addition of a site) for a finished product. Change to batch control arrangements (addition of a site) for a finished product. Minor changes:– to an approved test procedure for the finished product. Minor changes:– to an approved test procedure for active substance. Submission of a new Ph. Eur. CEP from a new manufacturer (replacement or addition) for a non-sterile: – active substance.
11 June 2024	Minor change to an approved test procedure for an active substance.
11 May 2024	Editorial change to SPC and QRD documents.
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.
24 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