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Post Authorisation Assessments

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

Easotic, Ear Drops Suspension for Dogs – Multidose

Vm 05653/5002

09 November 2026	Substantial changes in the updated version of the ASMF. Change in test procedure for active substance. Change in test procedure for active substance.
16 September 2026	Addition of 'Application site inflammation' to adverse events section under frequency category 'Very rare'.
15 June 2026	Addition of a quality testing site for the finished product.
13 May 2026	Alignment of the product information with version 9.0* of the QRD templates.
22 December 2025	Submission of a Ph. Eur. CEP for a new manufacturer of an active substance. Submission of a Ph. Eur. CEP for an active substance. Submission of a Ph. Eur. CEP for an active substance.
18 September 2025	Change in the specification parameters of an active substance.
01 April 2025	Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State.
02 October 2024	Other changes to the active substance: - Substantial changes in the updated version of the ASMF or the active substance part of the dossier. Other changes to the active substance: - Substantial changes in the updated version of the ASMF or the active substance part of the dossier.
11 May 2024	Changes to the quality part of the dossier: Deletion of - (a) a test procedure for the active substance or a starting material or reagent or intermediate of the active substance. Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter (e.g. deletion of an obsolete parameter) of an active substance.
23 January 2024	Minor changes: – to an approved test procedure for active substance, for the finished product.
04 May 2023	Changes to the labelling or the package leaflet which are not connected with the summary of product characteristics.
04 May 2023	Change to in-process tests or limits applied during the manufacture of the finished product.