



Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021,
please refer to the [EMA](#) website.

Osurnia Ear Gel for Dogs

Vm 10434/5002

• 06 November 2023	Change in contact details of a manufacturer of the active substance. Change in the address of an active substance master file holder. Update to the specifications and analytical methods of an active substance to comply with the current Ph. Eur. Deletion of a manufacturing site responsible for stability testing of the finished product. Deletion of a manufacturing site for an active substance.
• 11 August 2023	Approval of mock ups.
• 07 June 2023	Minor changes to an approved test procedure for the finished product.
• 19 October 2021	Changes in the SPC, Labelling or Package Leaflet intended to implement the outcome of a procedure concerning a periodic safety update report.
• 09 March 2021	Change in the name of QC testing of the active substance. Deletion of manufacturing site for an active substance.