



Post Authorisation Assessments

Otoxolan Ear Drops, Suspension for Dogs

•	25 June 2021	Addition of a site where batch control/testing takes place. Replacement of a primary packaging site of the finished product. Replacement of a secondary packaging site of the finished product. Replacement of a manufacturing site of the finished product.
•	11 June 2019	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	06 September 2018	Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	27 February 2018	Change in the RMS from UK to IE.
•	15 February 2018	Increase in the shelf-life of the finished product as packaged for sale, from 18 months to 2 years.
•	26 October 2017	Change in contact details for local representative.
•	18 October 2017	Minor change in the manufacturing process of the finished product. Change in the manufacturing process of the finished product.