Veterinary Medicines Directorate

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Post Authorisation Assessments

Orbax Flavoured Oral Suspension 30mg/ml for Dogs and Cats

•	10 April 2017	Change in the name of a manufacturer used in the manufacture of the active substance
•	16 February 2017	Changes to the labelling and package leaflet.
•	16 December 2016	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	04 December 2014	Update to the DDPS.
•	17 July 2014	Changes to tests related to the manufacturing process.
•	17 February 2014	Minor change to the shape of the vial.
•	17 February 2014	Change of manufacturer for the active substance.
•	20 December 2013	Renewal procedure.
•	22 November 2012	Change in the test procedure for the finished product. Change in test procedure for two excipients. Introduction of a new Pharmacovigilance system.
•	07 November 2012	To change the name of the distributor of the active substance and the name of the MAH from Schering-Plough Ltd to Intervet UK Ltd.
•	26 April 2012	To change the address of a manufacturing site.
•	07 September 2012	To change the name of a distributor of an active substance, to change the procedure of three tests.
•	26 April 2012	Change in the manufacture of a starting material.
•	21 April 2011	Change in test procedure of the finished product.
•	21 April 2011	Change in the specification parameters and/or limits of the finished product.
•	24 March 2011	Change in the name of the Marketing Authorisation Holder in Portugal from Schering-Plough II Veterinaria Lda to Intervet Portugal – Saude Animal Lda.
•	14 January 2011	Change in the name of the manufacturer for batch release.
•	12 January 2011	Change(s) to the therapeutic indication(s).
•	14 August 2009	Change of Marketing Authorisation Holder in France.