



Post Authorisation Assessments

Fipracyl Spot on Solution 402 mg for Extra Large Dogs

•	24 October 2017	Change to part of the (primary) packaging material not in contact with the finished product formulation. Change to more restrictive storage conditions of the active substance. Tightening of specification limits of an active substance used in the manufacturing process of the active substance.
•	09 June 2016	Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance. Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Deletion of a manufacturing site (for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)).
•	05 March 2014	Approval of mock-ups.
•	31 May 2013	Changes to an existing pharmacovigilance system as described in the DDPS.