



Post Authorisation Assessments

Vetflea 402 mg Spot-on Solution for Very Large Dogs

Vm 17902/4024

•	11 February 2020	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	12 October 2018	Change of specifications of a former non Pharmacopoeial active substance to comply with the Ph. Eur. monograph 2869.
•	17 September 2018	Change in RMS from UK to HU.
•	11 April 2018	Increase in the shelf-life of the finished product as packaged for sale, from 24 months to 36 months for the thermoformed pipettes.
•	28 March 2018	Renewal - UK as RMS
•	30 January 2018	Deletion of a manufacturing site for the finished product.
•	14 June 2017	Change in the name and address of a manufacturer used in the manufacture of the active substance. Addition of a manufacturer of the active substance.
•	09 December 2016	Minor change in the manufacturing process of the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	21 October 2015	To add an additional site of purification for the active substance.
•	30 July 2015	Change in the invented name of the product in Hungary and Romania only.
•	19 January 2015	Addition of an active substance manufacturer. Changes to the specification limits.
•	23 September 2014	Change to an in-process test applied during the manufacture of the finished product.
•	27 September 2012	Minor change in purification process of active substance, deletion of a non-significant specification parameter from the manufacturing, increase in batch size range of the active substance.
•	31 August 2012	Change in the primary packaging not in contact with the finished product formulation – addition of an individual blister for each pipette.