



Post Authorisation Assessments

Fleanil Duo 402 mg / 361.8 mg Spot-on Solution for Very Large Dogs

•	16 July 2021	Reduction of the shelf life of the finished product as packaged for sale from 3 years to 2 years.
•	07 May 2021	Addition of a new specification parameter to the specification with its corresponding test method.
•	06 January 2021	Change of specification(s) of a former non Pharmacopoeial active substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State.
•	22 October 2020	Change in the legal distribution category from NFA-VPS to AVM-GSL.
•	13 February 2020	Change in the SPC, labelling or package leaflet due to new data.
•	29 August 2019	Increase in the shelf-life of the finished product as packaged for sale, from 18 to 36 months.
•	30 July 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	09 July 2019	Addition of a manufacturer responsible for batch release of the finished product.