



Post Authorisation Assessments

Fleanil Duo 134 mg / 120.6 mg Spot-on Solution for Medium Dogs Vm 02000/4414

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| • | 18 November 2022 | Change in the manufacturer of an intermediate used in the manufacture of the active substance. Extension of the retest period of the active substance. |
| • | 28 October 2022 | Change in distributor details from Norbrook Laboratories (GB) Ltd, 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX, United Kingdom to Norbrook Laboratories Limited, Carnbane Industrial Estate, Newry, Co Down, BT35 6QQ, Northern Ireland. |
| • | 30 May 2022 | Renewal. |
| • | 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. |