



Post Authorisation Assessments

Florkem 300 mg/ml Solution for Injection for Cattle and Pigs Vm 15052/4046

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| • | 14 August 2024 | Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). |
| • | September 2022 | Addition of manufacturing site responsible for radiosterilisation of plastic vials. |
| • | 26 September 2022 | Change in the MAH address, from Ceva Animal Health Ltd, Unit 3, Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB to Ceva Animal Health Ltd, Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom. |
| • | 23 October 2019 | Update of the active substance master file. |
| • | 23 July 2018 | Quantitative composition changes to the immediate packaging of the active substance. Extension of a re-test period of the active substance. Minor change to the restricted part of an Active Substance Master File. |
| • | 09 May 2018 | Minor change to the manufacturing process of the finished product. Change to the in-process controls. |
| • | 17 January 2018 | Addition of a second manufacturing site responsible for the radio sterilisation. |
| • | 19 September 2017 | 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. |
| • | 06 January 2016 | Submission of a revised DDPS. |
| • | 19 June 2015 | Change to a specification limit of the finished product. |
| • | 13 February 2015 | Change to the MAH address in Slovakia and Czech Republic only. |
| • | 04 August 2014 | Renewal Procedure – UK Comment |
| • | 11 October 2013 | Changes to an existing pharmacovigilance system. |
| • | 12 July 2013 | Change in active substance manufacturer. |
| • | 13 February 2012 | To change the UK Marketing Authorisation Holder address. |
| • | 06 January 2012 | To change the name and address of the Marketing Authorisation Holder in Italy only, |
| • | 24 January 2011 | To change the name and address of the Marketing |

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| | | Authorisation Holder in Denmark only |
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