



Post Authorisation Assessments

Baytril Max 100 mg/ml Solution for Injection for Cattle and Pigs Vm 00879/4123

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| • | 21 March 2022 | Change in the name and/or address of the manufacturer of the finished product. |
| • | 03 June 2021 | Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. |
| • | 25 January 2021 | Change in the name of the manufacturer of the finished product. |
| • | 17 September 2020 | Change of MAH from Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD to Elanco Europe Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom. |
| • | 14 November 2018 | Change in the safety database of an existing pharmacovigilance system as described in the DDPS. |
| • | 01 June 2018 | Change to more restrictive storage conditions of the active substance. |
| • | 21 December 2017 | Replacement of a supplier of packaging components or devices. Change in the name of the manufacturer used in the manufacture of the active substance. |
| • | December 2017 | Change in the address of the marketing authorisation holder from Bayer plc, Animal Health Division, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA to Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire RG2 6AD |
| • | 07 December 2017 | Renewal UK as CMS |
| • | 20 July 2016 | Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH |
| • | 14 April 2014 | Change in the name of the marketing authorisation holder in France. |