



Post Authorisation Assessments

Prellim 0.075 mg/ml Solution for Injection for Cattle and Pigs Vm 31592/5003

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| • | 06 July 2024 | Product literature harmonisation with the reference product. |
| • | 09 November 2023 | Change in the name of the active substance manufacturer, address remains unchanged. |
| • | 21 April 2023 | Change in name of manufacturer of finished product responsible for batch release. Change in MAH name and address from Laboratorios Syva S.A.U., Avda. Párroco Pablo Díez, 49-57, 24010 LEÓN, ESPAÑA to Laboratorios SYVA S.A., C/ Marqués de la Ensenada, 16, 28004 Madrid, Spain. |
| • | 21 April 2023 | Change in name of manufacturer of the finished product. |
| • | 21 April 2023 | One-off alignment of the product information with version 1 of the national QRD templates. |
| • | 07 April 2022 | Changes in the SPC, Labelling or Package Leaflet for harmonization of the SPC between original and new concerned Member States. |
| • | 07 April 2022 | Deletion of a pack size(s) of the finished product. |
| • | 08 March 2022 | Variation to update the Active Substance Master File. |
| • | 13 October 2021 | Increase in batch size (from 50 L batch size to batch range of 50 L - 157.5 L) of the finished product. |
| • | 20 November 2020 | Change in distributor details from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street London EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead Surrey KT22 7LP. |
| • | 17 September 2019 | Submission of an updated ASMF for an approved manufacturer of the active substance. |
| • | 15 November 2018 | Change in the number of units (e.g. tablets, ampoules, etc.) in a pack within the range of the currently approved pack sizes of the finished product. |
| • | 10 April 2018 | Repeat Use application to add 4 new member states |
| • | 03 January 2018 | Change to a test procedure for the finished product. |
| • | 10 May 2017 | Updates to the approved Active Substance Master File. |
| • | 21 January 2016 | Deletion of a manufacturing site. |
| • | 06 October 2015 | Addition of a specification test for the active substance. Addition of a new active substance manufacturer. |
| • | 08 January 2015 | Change to a limit test to comply with a Ph. Eur. monograph. |
| • | 12 December 2014 | Change in test procedure for the finished product. |
| • | 23 April 2014 | Renewal. |

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| • | 11 December 2013 | Change of distributor. |
| • | 28 August 2013 | Change in the invented name of the product from 'Luteosyl 0.075 mg/ml Solution for Injection' to 'Prellim 0.075 mg/ml Solution for Injection'. |
| • | 26 August 2011 | To change the manufacturer of the finished product responsible for batch release. |
| • | 26 August 2011 | To change the manufacturer of the finished product. |
| • | 26 August 2011 | To change the name of the MAH from from Laboratorios SYVA, S.A. to Laboratorios SYVA, S.A.U. |