Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

# Post Authorisation Assessments

## Zermex 100 mg/ml LA Solution for Injection for Cattle

Vm 42058/5184

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| 12 September 2025 | Change in the primary packaging material not in contact with the finished product formulation. |
| 05 September 2025 | Updates to resistance warnings and statements. |
| 18 August 2025 | Change in the re-test period/storage period of the active substance- extension. |
| 05 June 2025 | Changes in the composition (excipients) of the finished product. |
| 01 April 2025 | Adverse events section updated, accepted and implemented. |
| 14 January 2025 | Change in legal entity of MA holder for Northern Ireland only from Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP to Zoetis Belgium S.A., 2nd Floor, Building 10, Cherrywood Business Park, Loughlinstown, Dublin 18, D18 T3Y1 Ireland. |
| 28 April 2024 | Updated CEP submitted for the manufacture of an active substance. |
| 12 April 2021 | Change in batch size range of the finished product. |
| 23 March 2021 | Change in distributor details. From Downland Marketing Limited, 15 Victoria Place, Carlisle, Cumbria, CA1 1EW to Downland Marketing Limited, Main Mill, Warwick Mill Business Centre, Warwick Bridge, Carlisle, Cumbria, CA4 8RR. |
| 22 October 2019 | Change in the address of the marketing authorisation holder 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. |
| 10 May 2019 | Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer |
| 12 December 2018 | Change to part of the (primary) packaging material not in contact with the finished product formulation.<br>Change in shape or dimensions of the container or closure (immediate packaging). |
| 13 November 2018 | Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS. |
| 30 January 2018 | Changes to the SPC/product labelling/package leaflet following an Article 35 referral. |
| 28 December 2017 | Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. |
| 13 January 2017 | Submission of a new or updated Eur. certificate of suitability. |
| 01 August 2016 | Variation to implement changes in the product information as requested by the RMS as a result of the review of PSUR. |
| 08 July 2015 | Submission of a new Ph. Eur. Certificate of Suitability. |
| 05 June 2015 | Change in the QPPV and/or QPPV contact details and/or back-up procedure |
| 10 December 2014 | Renewal. |

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| 4 July 2014 | Submission of an updated Ph. Eur. Certificate of Suitability. |
| 30 October 2013 | Change in name of manufacturer of the finished product and batch release. Change in QPPV contact details. |
| 23 October 2013 | Change in name of the MAH in Austria, Belgium, France and Luxembourg only. |
| 30 July 2013 | Change of MAH. |
| 4 November 2011 | Change in the name of a manufacturer of the finished product. |
| 2 September 2011 | Submission of new Ph. Eur. Certificate of Suitability. |
| 14 October 2010 | Change in the specifications of the finished product.<br>Change in the shelf-life of the finished product.<br>Change in the specifications/parameters of the finished product. |
| 26 May 2010 | To change the MAH from “Fort Dodge Animal Health Ltd” to “Pfizer Limited”. |