Veterinary Medicines Directorate

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

# Post Authorisation Assessments

## Advocin 180, 180mg/ml, Solution for Injection for Cattle

Vm 42058/3008

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| 15 October 2025 | Addition of a test procedure for the active substance. |
| 20 March 2025 | Deletion of a non-significant specification parameter for an active substance. |
| 12 March 2025 | Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).<br>Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. |
| 06 October 2023 | One-off alignment of the product information with version 9.0* of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004. |
| 17 January 2023 | Deletion of a test procedure for the finished product.<br>Deletion of a manufacturer of the finished product.<br>Deletion of a manufacturer of the finished product. |
| 29 March 2022 | Deletion of manufacturing site for an active substance.<br>Extension of a re-test period of the active substance. |
| 15 December 2021 | Addition to a test procedure for an excipient. |
| 08 January 2020 | 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. |
| 08 January 2020 | Replacement of a site for the manufacture of the active substance intermediate. |
| 07 November 2018 | Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS. |
| 06 September 2018 | Addition of a site where batch control/testing takes place.<br>Replacement of a manufacturer responsible for batch release of the finished product.<br>Addition of a secondary packaging site of the finished product.<br>Addition to a test procedure for the finished product.<br>Changes to a test procedure for the finished product.<br>Decrease in batch size range of the finished product.<br>Addition of an in-process control test.<br>Addition of a manufacturing site of the finished product. |
| 24 July 2018 | Change in the name of a manufacturer of the finished product, also responsible for batch release. |
| 08 August 2017 | Tightening of specification limits of an active substance used in the manufacturing process of the active substance.<br>Changes to a test procedure (including replacement * or addition*) for the active substance. |

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| | Change in the specification parameters and/or limits of the immediate packaging of the active substance.<br>Additional manufacturer of the active substance only for synthesis. |
| 18 July 2017 | Change in the name of the manufacturer of the finished product |
| 14 October 2015 | To add a site of secondary packaging for the finished product.<br>To add a new batch range for the finished product.<br>To add a site of manufacture and primary packaging for the finished product. |
| 05 June 2015 | Change in the QPPV and/or QPPV contact details and/or back-up procedure. |
| 06 March 2015 | Updates to the SPC and product literature. |
| 10 December 2014 | Change in the name of a site responsible for manufacturing and batch control and release of the finished product. |
| 20 December 2013 | Change to test procedures for the finished product. |
| 30 October 2013 | Addition of a finished product manufacturer responsible for batch release.<br>Update to the QPPV contact details. |
| 22 October 2013 | Change to the name of the MAH in Austria, Belgium, France and Luxembourg only. |
| 16 August 2013 | Change in distributor and MAH from Pfizer Limited to Zoetis UK Limited. |
| 13 April 2012 | Change to in process tests applied during the manufacture of the finished product. |
| 20 March 2012 | Change in product packaging components. |
| 13 February 2012 | Change to the name of the MAH in Spain only. |
| 16 June 2011 | Change to the name of the MAH in Poland only. |
| 04 March 2010 | Change in test procedure on the finished product. |
| 27 April 2009 | Change in test procedure on the finished product. |
| 29 December 2008 | Addition of a statement on use of fluoroquinolones to the SPC. |
| 12 May 2008 | Repeat use procedure. |
| 15 May 2006 | Renewal. |
| 09 May 2006 | Change of marketing authorisation holder (MAH) in Portugal only. |
| 12 August 2005 | Addition of a new therapeutic indication. |
| 07 July 2005 | Addition of a distributor. |
| 25 October 2004 | Change of name and address of a manufacturer. |
| 06 August 2003 | Addition of a new route of administration. |
| 11 July 2002 | Change of supplier of an intermediate in the manufacturing process of the active substance. |