

Post Authorisation Assessments

Labiprofen 150 mg/ml Solution for Injection for Cattle, Pigs and Horses Vm 32112/5000

01 April 2026	Update to adverse event reporting details in alignment with QRD version 9.1.
01 April 2026	Change in the Local Representative from: Cross Vetpharm Group UK Ltd. (T/A Bimeda), Unit 2, Bryn Cefni Industrial Park, Llangefni, Anglesey, LL77 7XA, United Kingdom, Tel: 01248 725400, e-mail: uksales@bimeda.com to: Interchem (Ireland) Ltd, Unit 29, Cookstown Industrial Estate, Dublin 24, Tel: 01 451 8959 and or e-mail: SADR@interchem.ie .
22 August 2025	Submission of a Ph. Eur. CEP for an active substance.
29 May 2025	Change in the shelf-life or storage conditions of the finished product: - Extension of the shelf life of the finished product.
4 July 2023	Changes in relation to MR/SR procedures: - Update of the dossier in preparation of a SRP/MRP/duplicate application in order to conform to the current legislation. 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.
22 April 2022	Repeat Use application to add 1 new member state
03 February 2022	Harmonisation of Changes to SPC, Labelling and Packaging leaflet between original and new concerned Member States after a repeat use procedure.
15 November 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance an already approved manufacturer.
11 November 2021	Tightening of specification limits of the finished product.
01 November 2021	Changes to the labelling and package leaflet.
26 May 2021	Repeat Use application to add 7 new member states