Veterinary Medicines Directorate

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

Post Authorisation Assessments

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

Vm 32112/3002

•	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.
•	30 May 2023	SRP to add 6 new member states
•	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