



Post Authorisation Assessments

Gabbrovet Multi 140 mg/ml Solution for Use in Drinking Water/Milk for Pre-ruminant Cattle and Pigs Vm 15052/5034

•	24 February 2023	Unlimited renewal
•	01 February 2023	<p>Change in the name or address or contact details of: a manufacturer or supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance or a quality control testing site (where specified in the dossier) where no European Pharmacopoeia (Ph. Eur.) Certificate of Suitability (CEP) is part of the approved dossier.</p> <p>Change in the name or address or contact details of: an active substance master file (ASMF) holder.</p> <p>Changes to the production process or the storage of active substance where no Ph. Eur. CEP is part of the approved dossier of an active substance (including starting material, reagent or intermediate): changes to quality control testing arrangements for the active substance: replacement or addition of a site where batch control or testing of the active substance takes place.</p> <p>Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter (e.g. deletion of an obsolete parameter) of an active substance, a starting material, or an intermediate or reagent used in the manufacturing process of the active substance.</p> <p>Minor changes: in the manufacturing process of an active substance.</p>
•	01 February 2023	Change in immediate packaging of the active substance.
•	03 January 2023	Change in the invented name of the veterinary medicinal product from Gabbrovet 140mg/ml Solution for Use in Drinking Water, Milk or Milk replacer for Pre-ruminant Cattle and Pigs to Gabbrovet Multi 140 mg/ml Solution for Use in Drinking Water/Milk for Pre-ruminant Cattle and Pigs.
•	02 December 2022	Changes to therapeutic indications.
•	10 November 2022	Change in immediate packaging of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product.
•	26 September 2022	Change in the MAH address, from Ceva Animal Health Ltd, Unit 3, Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB to Ceva Animal Health Ltd, Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.

•	22 September 2020	Replacement of a site where batch control/testing takes place.
•	22 November 2019	Changes to a test procedure for the finished product.
•	22 November 2019	Changes to a test procedure for the active substance.