



Post Authorisation Assessments

Eprinex Multi 5 mg/ml Pour-on Solution for Cattle, Sheep and Goats Vm 08327/3034

• 06 July 2024	Addition of a manufacturer for an active substance starting material.
• 22 June 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
• 14 May 2024	Deletion of a site of manufacture for a starting material. (NI)
• 26 February 2024	Site of manufacture for a starter material deleted. (GB)
• 16 January 2024	Addition of a new in-process test and limits applied during the manufacture of the active substance. (NI)
• 25 April 2023	Deletion of an alternative test procedure for a reagent used in the manufacture of the active substance. Minor changes to a test procedure for a reagent used in the manufacturing process of the active substance. (NI)
• 11 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
• 30 December 2022	Deletion of an alternative test procedure for a reagent used in the manufacture of the active substance. Minor changes to a test procedure for a reagent used in the manufacturing process of the active substance. (GB)
• 21 December 2022	Addition of a new in-process test and limits applied during the manufacture of the active substance. (GB)
• 30 September 2022	Addition of therapeutic indications. Addition of therapeutic indications. Addition/revision of prudent use recommendations to the SPC and corresponding sections of the product literature.
• 22 February 2022	Change in the name and address of a manufacturer used in the manufacture of the active substance.
• 22 October 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
• 03 September 2021	Renewal - UK as CMS.
• 28 May 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
• 23 April 2020	Change in the invented name of the veterinary medicinal product from Eprivalan vet 5 mg/ml pour-on for beef and dairy cattle, sheep and goats to Eprinex vet 5 mg/ml pour-on for beef and dairy cattle, sheep and goats for DK, FI, NO and SE.
• 05 November 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
• 15 August 2019	Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products.

<ul style="list-style-type: none"> • 16 November 2018 	<p>Change in the name and address of the marketing authorisation holder from Merial Animal Health Limited, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG, United Kingdom to Boehringer Ingelheim Animal Health UK Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom.</p>
<ul style="list-style-type: none"> • 01 August 2018 	<p>Repeat Use application to add 17 new member states</p>
<ul style="list-style-type: none"> • 10 January 2018 	<p>Deletion of manufacturing sites for an active substance.</p>
<ul style="list-style-type: none"> • 20 October 2017 	<p>Addition of measuring / administration device without CE markings which is not an integrated part of the primary packaging.</p>
<ul style="list-style-type: none"> • 01 June 2017 	<p>Addition of a new in-process test and limit applied during the manufacture of the active substance. Minor change in the manufacturing process of the active substance.</p>
<ul style="list-style-type: none"> • 21 December 2016 	<p>Change to part of the (primary) packaging material not in contact with the finished product formulation. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Change in shape or dimensions of the container or closure (immediate packaging).</p>