

VPA22020/053/001

Baytril Max 100 mg/ml Solution for Injection for Cattle and Pigs

Variation	Summary	Date
Vet - B44 b)	VNRA - Vet - B44 b) - - Vet - B44 b) - Submission of a Ph. Eur. CEP for:— active substance;— starting material, reagent or intermediate used in the manufacturing process of the active substance; — excipient - New certificate	24/09/25
Vet - G.I.Z	VRA-S - Vet - G.I.Z - Change(s) in the SPC, labelling or package leaflet intended to implement the outcome of a procedure - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a Union interest referral procedure according to Article 83 of Regulation (EU) 2019/6 . Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	25/08/25
Vet - G.I.18	VRA-S - Vet - G.I.18 - - Vet - G.I.18 - 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 authorised in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	25/08/25
Vet - A1 e)	VNRA - Vet - A1 e) - - Vet - A1 e) Administrative changes - Change in the name or address of a manufacturer or importer of the finished product (including batch release or quality control testing sites)	14/08/25
Vet - C6	VNRA - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17 - C6 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17	12/11/24
Vet - C1	VNRA - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) - C1 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	12/11/24
A.5.b	IA - A.5.b - b) The activities for which the manufacturer/importer is responsible do not include batch release - A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release	24/02/22