VPA22664/150/001

Solantel 200 mg/ml Pour-On Solution for Cattle

Variation	Summary	Date
Vet - B3 d)	VNRA - Vet - B3 d) - - Vet - B3 d) - 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;— an intermediate or reagent used in the manufacturing process of the active substance	10/11/26
Vet - F.II.d.2 b)	VRA-R - Vet - F.II.d.2 b) - - Vet - F.II.d.2 b) - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	09/01/26
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	01/09/25
Vet - G.I.3 b)	VRA-R - Vet - G.I.3 b) - b) Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon - G.I.3 b) Safety, Efficacy, Pharmacovigilance changes - Change(s) in the SPC, labelling or package leaflet intended to implement the outcome of a procedure or recommendations from the competent authority or the Agency concerning risk management measures in pharmacovigilance related to veterinary medicinal products - Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon	26/06/24
Vet - B27 a)	VNRA - Vet - B27 a) - a) Tightening of in-process limits - B27 a) Changes to the quality part of the dossier: Change to in-process tests or limits applied during the manufacture of the finished product: — tightening of in-process limits	18/12/23
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	25/07/23
Vet - B43	VNRA - Vet - B43 - Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible - B43 Changes to the quality part of the dossier: Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible	28/03/22