

VPA10387/019/001

**DECTOMAX 10 mg/ml Solution for Injection for Cattle, Sheep and Pigs**

Variation	Summary	Date
Vet - B3 a)	VNRA - Vet - B3 a) - a) Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier) - B3 a) Changes to the quality part of the dossier: Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier)	28/02/24
Vet - F.I.a.1 e)	VRA-S - Vet - F.I.a.1 e) - e) Introduction of a new manufacturer of the active substance that is not supported by an ASMF and requires significant update to the relevant active substance section of the dossier - F.I.a.1 e) - Quality Changes - Active Substance - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a new manufacturer of the active substance that is not supported by an ASMF and requires significant update to the relevant active substance section of the dossier	27/02/24
Vet - G.I.18	VRA-S - Vet - G.I.18 - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) 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 - G.I.18 Safety, Efficacy, Pharmacovigilance changes - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) 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	08/01/24
Vet - F.I.d. z)	VRA-S - Vet - F.I.d. z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.I.d. z) Quality Changes - Active Substance - Stability - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	16/02/23

Vet - F.II.d.2 z)	VRA-S - Vet - F.II.d.2 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.d.2 z) Quality Changes - Finished Product -Control of finished product - Change in test procedure for the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	17/01/23
Vet - F.II.d.1 z)	VRA-S - Vet - F.II.d.1 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.d.1 z) Quality Changes - Finished Product -Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	17/01/23
Vet - B21	VNRA - Vet - B21 - Replacement or addition of a secondary packaging site of a finished product - B21 Changes to the quality part of the dossier: Replacement or addition of a secondary packaging site of a finished product	26/09/22
Vet - B21	VNRA - Vet - B21 - Replacement or addition of a secondary packaging site of a finished product - B21 Changes to the quality part of the dossier: Replacement or addition of a secondary packaging site of a finished product	26/09/22