VPA22033/008/001

Deltadot 10 mg/ml Pour-on Solution for Cattle and Sheep

Variation	Summary	Date
Vet - F.II.e.1 b) 1.	VRA-R - Vet - F.II.e.1 b) 1. - - Vet - F.II.e.1 b) 1. - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms	12/11/26
Vet - B22	VNRA - Vet - B22 - - Vet - B22 - Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product	28/08/26
Vet - B24 a)	VNRA - Vet - B24 a) - - Vet - B24 a) - Replacement or addition of a manufacturer responsible for: batch release including batch control or testing of a sterile or non-sterile finished product	25/08/26
Vet - B26 c)	VNRA - Vet - B26 c) - - Vet - B26 c) - Change in the batch size (including batch size ranges) of the finished product: downscaling down to 10-fold compared to the originally approved batch size of an immediate release oral pharmaceutical forms or to non-sterile liquid based pharmaceutical form	25/08/26
Vet - B21	VNRA - Vet - B21 - - Vet - B21 - Replacement or addition of a secondary packaging site of a finished product	25/08/26
Vet - F.II.b.1 c)	VRA-R - Vet - F.II.b.1 c) - - Vet - F.II.b.1 c) - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products	25/08/26
Vet - B20	VNRA - Vet - B20 - - Vet - B20 - Replacement or addition of a primary packaging site of a non-sterile finished product	31/07/26
Vet - C1	VNRA - Vet - C1 - - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	09/02/26
Vet - C6	VNRA - Vet - C6 - - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex	09/02/26
Vet - B39	VNRA - Vet - B39 - Change in any part of the primary packaging material not in contact with the finished product formulation - B39 Changes to the quality part of the dossier: Change in any part of the primary packaging material not in contact with the finished product formulation (such as change of colour due to different plastic used for flip-off caps, colour code rings on ampoules or change of needle shield)	12/06/24
Vet - B37	VNRA - Vet - B37 - Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product - B37 Changes to the quality part of the	05/12/23

	dossier: Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product	
Vet - B3 k)	VNRA - Vet - B3 k) - k) Deletion of a non-significant in-process test (finished product manufacture) - B3 k) Changes to the quality part of the dossier: Deletion of a non-significant in-process test (e.g. deletion of an obsolete test) during the manufacture of the finished product	16/11/23
Vet - F.II.b.5 z)	VRA-R - Vet - F.II.b.5 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.b.5 z) Quality Changes - Finished Product -Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	15/11/23
Vet - B39	VNRA - Vet - B39 - Change in any part of the primary packaging material not in contact with the finished product formulation - B39 Changes to the quality part of the dossier: Change in any part of the primary packaging material not in contact with the finished product formulation (such as change of colour due to different plastic used for flip-off caps, colour code rings on ampoules or change of needle shield)	25/10/23
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	16/08/23
Vet - B22	VNRA - Vet - B22 - Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product - B22 Changes to the quality part of the dossier: Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product	29/11/22
Vet - B35 a)	VNRA - Vet - B35 a) - a) Tightening of specification limits - B35 a) Changes to the quality part of the dossier: Change in the specification parameters or limits of the immediate packaging of the finished product: — tightening of specification limits	30/03/22