VPA22020/022/001

CLiK Extra 65 mg/ml Pour-On Suspension for Sheep

Variation	Summary	Date
Vet - B43	VNRA - Vet - B43 - - Vet - B43 - Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible	21/10/26
Vet - C9	VNRA - Vet - C9 - - Vet - C9 - Editorial changes to SPC, package leaflet or labelling if inclusion in an upcoming procedure is not possible	12/06/26
Vet - B43	VNRA - Vet - B43 - - Vet - B43 - Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible	06/11/25
Vet - B35 b)	VNRA - Vet - B35 b) - - Vet - B35 b) -Change in the specification parameters or limits of the immediate packaging of the finished product: addition of a new specification parameter to the specification with its corresponding test method	06/11/25
Vet - F.II.e.5 c)	VRA-R - Vet - F.II.e.5 c) - - Vet - F.II.e.5 c) - Change in pack size of the finished product - Change in the fill weight/fill volume of non parenteral multi dose (or single-dose, partial use) products	05/11/25
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	05/11/25
Vet - F.IV.1 a) 1.	VRA-R - Vet - F.IV.1 a) 1. - - Vet - F.IV.1 a) 1. - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device without CE marking	05/11/25
Vet - F.II.e.4 a)	VRA-S - Vet - F.II.e.4 a) - - Vet - F.II.e.4 a) - Change in shape or dimensions of the container or closure (immediate packaging) - The change in shape or dimensions concerns a fundamental part of the packaging material, which may have a significant impact on the delivery, use, safety or stability of the finished product	05/11/25
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	05/11/25
Vet - F.II.e.1 a) 1.	VRA-R - Vet - F.II.e.1 a) 1. - - Vet - F.II.e.1 a) 1. - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Semi-solid and non-sterile liquid pharmaceutical forms	05/11/25
Vet - F.I.d.1 c)	VRA-R - Vet - F.I.d.1 c) - - Vet - F.I.d.1 c) - Change in the re-test period/storage period of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is	30/10/25

	part of the approved dossier - Extension or introduction of a re-test period/storage period supported by real time data	
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	25/02/25
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)	09/10/24
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	09/10/24
Vet - F.I.a.1 a)	VRA-S - Vet - F.I.a.1 a) - a) Introduction of a manufacturer of the active substance supported by an ASMF - F.I.a.1 a) - 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 manufacturer of the active substance supported by an ASMF	27/04/23
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	06/03/23
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,	06/03/23

	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	
B.II.b.3.a	IB - B.II.b.3.a - a) Minor change in the manufacturing process - B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process	16/02/22
B.II.b.3.a	IB - B.II.b.3.a - a) Minor change in the manufacturing process - B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process	16/02/22
B.II.b.3.a	IB - B.II.b.3.a - a) Minor change in the manufacturing process - B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process	16/02/22
B.II.b.3.a	IB - B.II.b.3.a - a) Minor change in the manufacturing process - B.II.b.3.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process	16/02/22
B.II.e.4.a	IA - B.II.e.4.a - a) Non-sterile medicinal products - B.II.e.4.a - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products	16/02/22