VPA10815/024/001

Eprecis 20 mg/ml solution for injection for cattle, sheep and goats

Variation	Summary	Date
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)	25/03/24
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	25/03/24
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	29/09/23
Vet - G.I.7 a)	VRA-E - Vet - G.I.7 a) - a) Addition of a new therapeutic indication or modification of an approved one - G.I.7 a) Safety, Efficacy, Pharmacovigilance changes - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	29/09/23
Vet - A1 a)	VNRA - Vet - A1 a) - a) Change in the name or address or contact details of the marketing authorisation holder - A1 a) Administratvie changes: Change in the name or address or contact details of the marketing authorisation holder	31/07/23
Vet - F.I.f.1	VRA-S - Vet - F.I.f.1 - 1. Substantial changes in the updated version of the ASMF or the active substance part of the dossier - F.I.f.1 Quality Changes - Active Substance - Other changes to the active substance - Substantial changes in the updated version of the ASMF or the active substance part of the dossier	26/06/23
Vet - F.II.b.1 d)	VRA-S - Vet - F.II.b.1 d) - d) Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile veterianry medicinal products	05/10/22

	(including those that are aseptically manufactured) excluding biological/ immunological veterinary medicinal products - F.II.b.1 d) Quality Changes - Finished Product -Manufacture - 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, and secondary packaging, for sterile veterianry medicinal products (including those that are aseptically manufactured) excluding biological/ immunological veterinary medicinal products	
B.II.e.2.c	IA - B.II.e.2.c - c) Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	02/02/22
B.II.e.2.c	IA - B.II.e.2.c - c) Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	02/02/22
B.II.e.2.c	IA - B.II.e.2.c - c) Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	02/02/22
B.II.e.2.c	IA - B.II.e.2.c - c) Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	02/02/22
B.II.e.2.c	IA - B.II.e.2.c - c) Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	02/02/22
B.II.e.2.c	IA - B.II.e.2.c - c) Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - B.II.e.2.c - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in the specification parameters and/or limits of the immediate packaging of the finished product -	02/02/22

	Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	
B.II.b.3.z	IB - B.II.b.3.z - z Other variation - B.II.b.3.z - 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 - Other variation	02/02/22
B.II.b.5.z	IB - B.II.b.5.z - z Other variation - B.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 variation	02/02/22