VPA10988/018/003

Rilexine 600 mg Tablets for dogs

Variation	Summary	Date
Vet - F.II.d.1 a)	VRA-S - Vet - F.II.d.1 a) - a) Change outside the approved specifications limits range - F.II.d.1 a) Quality Changes - Finished Product -Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	09/07/25
Vet - F.II.d.1 a)	VRA-S - Vet - F.II.d.1 a) - a) Change outside the approved specifications limits range - F.II.d.1 a) Quality Changes - Finished Product -Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	09/07/25
Vet - F.II.b.5 b)	VRA-S - Vet - F.II.b.5 b) - b) Widening of the approved IPC limits, which may have a significant effect on overall quality of the finished product - F.II.b.5 b) Quality Changes - Finished Product -Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Widening of the approved IPC limits, which may have a significant effect on overall quality of the finished product	09/07/25
Vet - F.II.b.5 b)	VRA-S - Vet - F.II.b.5 b) - b) Widening of the approved IPC limits, which may have a significant effect on overall quality of the finished product - F.II.b.5 b) Quality Changes - Finished Product -Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Widening of the approved IPC limits, which may have a significant effect on overall quality of the finished product	09/07/25
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	01/08/24
Vet - F.II.c.2 b)	VRA-S - Vet - F.II.c.2 b) - b) Other changes to a test procedure (including replacement or addition) - F.II.c.2 b) Quality Changes - Finished Product -Control of excipients-Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition)	06/07/23