VPA10987/124/001

Gastazole 370 mg/g oral paste for horses

Variation	Summary	Date
Vet - B39	VNRA - Vet - B39 - - Vet - B39 - 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)	23/03/26
Vet - B37	VNRA - Vet - B37 - - Vet - B37 - Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product	22/12/25
Vet - C10 b)	VNRA - Vet - C10 b) - - Vet - C10 b) - Changes to the labelling or the package leaflet which shall not be connected with the SPC: other changes	12/08/25
Vet - B37	VNRA - Vet - B37 - - Vet - B37 - Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product	21/07/25
Vet - B37	VNRA - Vet - B37 - - Vet - B37 - Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product	21/07/25
Vet - B37	VNRA - Vet - B37 - - Vet - B37 - Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product	21/07/25
Vet - B37	VNRA - Vet - B37 - - Vet - B37 - Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product	21/07/25
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	08/07/25
Vet - B37	VNRA - Vet - B37 - - Vet - B37 - Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product	08/07/25
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)	04/04/25

	2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	
Vet - B43	VNRA - Vet - B43 - Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible - B43 Changes to the quality part of the dossier: Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible	23/05/24
Vet - F.II.d.2 b)	VRA-E - Vet - F.II.d.2 b) - b) Other changes to a test procedure (including replacement or addition) - F.II.d.2 b) Quality Changes - Finished Product -Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	11/12/23
Vet - F.II.a.3 b) 4.	VRA-E - Vet - F.II.a.3 b) 4. - b) Other excipients 4. Change that is supported by a bioequivalence study - F.II.a.3 b) 4. Quality Changes - Finished Product - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Change that is supported by a bioequivalence study	11/12/23
Vet - F.II.d.1 a)	VRA-E - 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	11/12/23
Vet - F.II.b.5 z)	VRA-E - 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	11/12/23
Vet - F.II.b.3 h)	VRA-E - Vet - F.II.b.3 h) - h) Change in the holding time of an intermediate or bulk product (if applicable) - F.II.b.3 h) 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 - Change in the holding time of an intermediate or bulk product (if applicable)	11/12/23
Vet - F.II.b.4 z)	VRA-E - Vet - F.II.b.4 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.4 z) Quality Changes - Finished Product -Manufacture - Change in the batch size (including batch size ranges) of the finished product - Other changes under this code level, e.g. variations	11/12/23

	outlined in section 6 and 7 of EMA/CMDv/7381/2021	
Vet - F.II.b.3 b)	VRA-E - Vet - F.II.b.3 b) - b) Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product - F.II.b.3 b) 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 - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product	11/12/23
Vet - F.II.d.2 b)	VRA-E - Vet - F.II.d.2 b) - b) Other changes to a test procedure (including replacement or addition) - F.II.d.2 b) Quality Changes - Finished Product -Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	04/12/23
Vet - F.II.a.3 b) 4.	VRA-E - Vet - F.II.a.3 b) 4. - b) Other excipients 4. Change that is supported by a bioequivalence study - F.II.a.3 b) 4. Quality Changes - Finished Product - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Change that is supported by a bioequivalence study	04/12/23
Vet - F.II.d.1 a)	VRA-E - 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	04/12/23
Vet - F.II.b.5 z)	VRA-E - 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	04/12/23
Vet - F.II.b.3 h)	VRA-E - Vet - F.II.b.3 h) - h) Change in the holding time of an intermediate or bulk product (if applicable) - F.II.b.3 h) 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 - Change in the holding time of an intermediate or bulk product (if applicable)	04/12/23
Vet - F.II.b.4 z)	VRA-E - Vet - F.II.b.4 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.4 z) Quality Changes - Finished Product -Manufacture - Change in the batch size	04/12/23

	(including batch size ranges) of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	
Vet - F.II.b.3 b)	VRA-E - Vet - F.II.b.3 b) - b) Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product - F.II.b.3 b) 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 - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product	04/12/23
Vet - B3 f)	VNRA - Vet - B3 f) - f) Deletion of one of the authorised bulk or final containers (including packaging of an active substance) or immediate packaging of the finished product that does not lead to the complete deletion of a strength or pharmaceutical form - B3 f) Changes to the quality part of the dossier: Deletion of one of the authorised bulk or final containers (including packaging of an active substance) or immediate packaging of the finished product that does not lead to the complete deletion of a strength or pharmaceutical form	21/11/23
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)	20/11/23
Vet - F.II.d.2 b)	VRA-R - Vet - F.II.d.2 b) - b) Other changes to a test procedure (including replacement or addition) - F.II.d.2 b) Quality Changes - Finished Product -Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	20/11/23
Vet - F.II.a.3 b) 4.	VRA-S - Vet - F.II.a.3 b) 4. - b) Other excipients 4. Change that is supported by a bioequivalence study - F.II.a.3 b) 4. Quality Changes - Finished Product - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Change that is supported by a bioequivalence study	20/11/23
Vet - F.II.d.1 a)	VRA-S - Vet - F.II.d.1 a) - a) Change outside the approved	20/11/23

	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	
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	20/11/23
Vet - F.II.b.3 h)	VRA-R - Vet - F.II.b.3 h) - h) Change in the holding time of an intermediate or bulk product (if applicable) - F.II.b.3 h) 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 - Change in the holding time of an intermediate or bulk product (if applicable)	20/11/23
Vet - F.II.b.4 z)	VRA-R - Vet - F.II.b.4 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.4 z) Quality Changes - Finished Product -Manufacture - Change in the batch size (including batch size ranges) of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	20/11/23
Vet - F.II.b.3 b)	VRA-S - Vet - F.II.b.3 b) - b) Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product - F.II.b.3 b) 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 - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product	20/11/23
Vet - A2	VNRA - Vet - A2 - Change in the (invented) name of the veterinary medicinal product - A2 Administratvie changes: Change in the (invented) name of the veterinary medicinal product	02/11/23
Vet - A2	VNRA - Vet - A2 - Change in the (invented) name of the veterinary medicinal product - A2 Administratvie changes: Change in the (invented) name of the veterinary medicinal product	15/11/22
Vet - B44(Do not use)	VNRA - Vet - B44 - Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance, starting material, reagent or intermediate, excipient - B44 Changes to the quality part	06/10/22

	of the dossier: Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: — active substance; — starting material, reagent or intermediate used in the manufacturing process of the active substance; — excipient	