VPA22622/023/010

Vetoryl 20 mg hard capsules for dogs

Variation	Summary	Date
Vet - B12 b)	VNRA - Vet - B12 b) - - Vet - B12 b) - Minor changes: - to an approved test procedure — for the immediate packaging of the active substance or the finished product	31/10/25
Vet - B28 a)	VNRA - Vet - B28 a) - - Vet - B28 a) - Change in the specification parameters or limits of an excipient tightening of specification limits	31/10/25
Vet - F.V.b 1. c)	VRA-S - Vet - F.V.b 1. c) - - Vet - F.V.b 1. c) - Harmonisation o the quality dossier Harmonisation of the quality dossier for the same purely national products and/or the same products approved in MR/DC procedures which are owned by the same MAH not participating in a former union interest referral procedure or SPC harmonisation procedure	10/09/25
Vet - F.I.f.1	VRA-S - Vet - F.I.f.1 - - Vet - F.I.f.1 - Substantial changes in the updated version of the ASMF or the active substance part of the dossier	21/07/25
Vet - B11 d)	VNRA - Vet - B11 d) - - Vet - B11 d) - Change in the specification parameters or limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance or of the immediate packaging of the active substance: addition of a new specification parameter to the specification with its corresponding test method for an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance	01/07/25
Vet - B11 d)	VNRA - Vet - B11 d) - - Vet - B11 d) - Change in the specification parameters or limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance or of the immediate packaging of the active substance: addition of a new specification parameter to the specification with its corresponding test method for an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance	01/07/25
Vet - B3 d)	VNRA - Vet - B3 d) - - Vet - B3 d) - Changes to the quality part of the dossier: Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) of — an active substance;— a starting material;— an intermediate or reagent used in the manufacturing process of the active substance	01/07/25
Vet - B3 e)	VNRA - Vet - B3 e) - - Vet - B3 e) - Changes to the quality part of the dossier: Deletion of a test procedure — for the active substance or a starting material, reagent or intermediate of the active substance;— for the immediate packaging of the active substance;— for an excipient or the finished product;— for the	01/07/25

	immediate packaging of the finished product	
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	01/07/25
Vet - B11 d)	VNRA - Vet - B11 d) - - Vet - B11 d) - Change in the specification parameters or limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance or of the immediate packaging of the active substance: addition of a new specification parameter to the specification with its corresponding test method for an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance	01/07/25
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	01/07/25
Vet - G.I.15 z)	VRA-R - Vet - G.I.15 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - G.I.15 z) Safety, Efficacy, Pharmacovigilance changes - Changes to the labelling or the package leaflet which are not connected with the summary of product characteristics - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	28/05/25
Vet - C10 a)	VNRA - Vet - C10 a) - a) Administrative information concerning the holder’s representative - C10 a) Changes to the safety, efficacy and pharmacovigilance part of the dossier: Changes to the labelling or the package leaflet which shall not be connected with the SPC: — administrative information concerning the holder’s representative	19/05/25
Vet - F.III.1 a) z.	VRA-R - Vet - F.III.1 a) z. - a) European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.III.1 a) z. Quality Changes - CEP/TSE/MONOGRAPHS -Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability: -For an active substance -For a starting material/reagent/intermediate used in the manufacturing process of the active substance -For an excipient European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	13/03/25