

VPA10981/004/001

Tylo 200 mg/ml solution for injection

Variation	Summary	Date
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	09/06/23
B.II.a.3.b.1	IA - B.II.a.3.b.1 - 1. Any minor adjustment of the quantitative composition of the finished product with respect to excipients - B.II.a.3.b.1 - QUALITY CHANGES - FINISHED PRODUCT - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Any minor adjustment of the quantitative composition of the finished product with respect to excipients	02/09/22
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	12/08/22
B.II.d.2.d	IB - B.II.d.2.d - d) Other changes to a test procedure (including replacement or addition) - B.II.d.2.d - 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)	02/02/22
B.II.d.1.h	IB - B.II.d.1.h - h) Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product* - B.II.d.1.h - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product*	02/02/22