

VPA22664/111/001

**Taurador 5 mg/ml Pour-on Solution for Cattle**

Variation	Summary	Date
Vet - F.I.a.1 a)	VRA-S - Vet - F.I.a.1 a) - - Vet - F.I.a.1 a) - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF	28/07/25
Vet - F.II.b.3 a)	VRA-R - Vet - F.II.b.3 a) - a) Minor change in the manufacturing process - F.II.b.3 a) 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 - Minor change in the manufacturing process	27/11/24
Vet - B37	VNRA - Vet - B37 - Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product - B37 Changes to the quality part of the dossier: Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product	01/03/24
Vet - B37	VNRA - Vet - B37 - Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product - B37 Changes to the quality part of the dossier: Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product	01/03/24
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	19/09/23
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	19/07/23
Vet - B3 d)	VNRA - Vet - B3 d) - d) Deletion of a non-significant specification parameter (active substance, starting material, intermediate - 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	02/05/23

Vet - B11 b)	VNRA - Vet - B11 b) - b) Tightening of specification limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance - B11 b) Changes to the quality part of the dossier: 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 — tightening of specification limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance	08/02/23
Vet - B11 d)	VNRA - Vet - B11 d) - d) Addition of a new specification parameter to the specification with its corresponding test method - B11 d) Changes to the quality part of the dossier: 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	08/02/23
Vet - B11 d)	VNRA - Vet - B11 d) - d) Addition of a new specification parameter to the specification with its corresponding test method - B11 d) Changes to the quality part of the dossier: 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	08/02/23
Vet - B11 b)	VNRA - Vet - B11 b) - b) Tightening of specification limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance - B11 b) Changes to the quality part of the dossier: 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 — tightening of specification limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance	08/02/23
Vet - B11 d)	VNRA - Vet - B11 d) - d) Addition of a new specification parameter to the specification with its corresponding test method - B11 d) Changes to the quality part of the dossier: 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	08/02/23