

VPA10791/014/001

DORAXX 100 mg/ml solution for injection for cattle, pigs and sheep

Variation	Summary	Date
Vet - F.I.d.1 c)	VRA-R - Vet - F.I.d.1 c) - c) Extension or introduction of a re-test period/storage period supported by real time data - F.I.d.1 c) Quality Changes - Active Substance - Stability -Change in the re-test period/storage period of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Extension or introduction of a re-test period/storage period supported by real time data	27/04/23
Vet - B9 a)	VNRA - Vet - B9 a) - a) Up to 10-fold increase compared to the originally approved batch size - B9 a) Changes to the quality part of the dossier: Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance — up to 10-fold increase compared to the originally approved batch size	19/04/23
Vet - B9 a)	VNRA - Vet - B9 a) - a) Up to 10-fold increase compared to the originally approved batch size - B9 a) Changes to the quality part of the dossier: Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance — up to 10-fold increase compared to the originally approved batch size	12/04/23