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Post Authorisation Assessments

Sedanol 40 mg/ml Solution for Injection for Pigs Vm 57446/4014

17 March 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (GB)
30 January 2025	Alignment of the product information with version 9.0* of the QRD templates.
23 October 2024	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance.
27 October 2024	Change in distributor details from Chanelle Vet UK Ltd. 483 Green Lanes, London, N13 4BS to DUGV(UK) Ltd., Union House, 111 New Union Street, Coventry, CV1 2NT. Update of Mock ups.
August 2024	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance.
27 March 2024	Unlimited renewal
03 November 2023	Change in distributor details from Chanelle Animal Health Ltd, 7 Rodney Street, Liverpool, L1 9HZ to Chanelle Vet UK Ltd, 483 Green Lanes, London, N13 4BS.
01 September 2023	Change in the name or address or contact details of: a manufacturer (including batch release sites).
09 June 2023	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
23 January 2023	Change in MAH from Richter Pharma AG, Feldgasse 19, 4600 Wels, Austria to VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria.
09 November 2021	Required updates to the SPC and product literature.
10 May 2021	Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
21 December 2020	Changes to the SPC/product labelling/package leaflet following an Article 35 referral.
04 June 2020	Repeat Use Application to add 4 new member states.