Veterinary Medicines Directorate

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Post Authorisation Assessments

Ocnil 400 mg/g Powder for Use in Drinking Water

Vm 32509/4021

•	11 December 2023	Submission of an updated certificate of suitability. (NI)
•	15 March 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer.
•	30 January 2023	Updated certificate of suitability from an already approved manufacturer.
•	30 January 2023	Updated certificate of suitability from an already approved manufacturer.
•	11 January 2023	Change of Distributor from Vetpharma Animal Health, S.L to DUGV (UK) Ltd, Union House, 111 New Union Street, Coventry, Warwickshire, CV1 2NT.
•	08 December 2022	Variation to add the company Duggan Veterinary Supplies Ltd. to act as Local Representative in Ireland and DUGV (UK) Ltd to act as local representative in UK.
•	30 September 2022	Updated certificate of suitability from an already approved manufacturer.
•	18 August 2022	Renewal.
•	July 2022	Variation to add the company Duggan Veterinary Supplies Ltd. to act as Local Representative in Ireland and DUGV (UK) Ltd to act as local representative in UK.
•	21 October 2021	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	17 March 2021	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer. Change in the specification parameters and/or limits of an active substance.
•	01 October 2020	Change in the specification limits of the finished product.
•	18 August 2020	Changes to the labelling and/or package leaflet.
•	07 April 2020	Changes to the labelling and package leaflet. Change in distributor details from Vetpharma Animal Health, S.L., Les Corts, 23, 08028 Barcelona, Spain to Duggan Veterinary Supplies Ltd, Holycross, Thurles, Co Tipperary, Ireland, E41 A093.
•	07 May 2019	Repeat Use application to add one new member state
•	09 July 2018	Change in the fill volume of the finished product. Change in the Summary of Product Characteristics, Labelling or Package Leaflet following a procedure in accordance with Articles 34 of Directive 2001/82/EC (referral procedure).
•	08 May 2018	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.