Veterinary Medicines Directorate

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Post Authorisation Assessments

Dinalgen 150 mg/ml Solution for Injection for Cattle, Pigs and Horses

Vm 46037/4003

•	17 November 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF. (NI)
•	05 April 2022	Change in the address of the marketing authorisation holder from Ecuphar Veterinaria S.L.U. Avda. Rio de Janeiro 60-66 Planta 13, 08016 Barcelona (Spain) to Ecuphar Veterinaria S.L.U. C/Cerdanya, 10-12 Planta 6º, 08173 Sant Cugat del Vallés, Barcelona (Spain).
•	09 April 2021	Changes to the labelling and/or package leaflet.
•	27 October 2020	Changes to the labelling and package leaflet. Change in distributor details from Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD to Duggan Veterinary Supplies Ltd, Holycross, Thurles, County Tipperary, E41 A093, Ireland.
•	15 April 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	04 April 2019	Changes to the labelling and/or package leaflet. Change in distributor details from Bayer plc, Animal Health Division, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA, United Kingdom to Bayer plc, 400 South Oak Way, Green Park, Reading, RG2 6AD, United Kingdom.
•	15 January 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	16 October 2017	Introduction of a new pharmacovigilance system.
•	02 December 2016	Change of Marketing Authorisation Holder from Laboratorios Dr. Esteve, S.A. to Ecuphar Veterinaria S.L.U.
•	09 July 2015	Submission of an updated certificate of suitability.
•	20 May 2015	Renewal – UK as CMS.
•	11 December 2014	Approval of mock-ups.
•	14 October 2014	Addition of a UK distributor.
•	26 September 2014	To replace the approved container stopper with a new one.
•	12 June 2014	To submit a new updated European Pharmacopeia Certificate of Suitability for the active substance.
•	09 May 2014	Change in the shelf-life of the finished product from 36 months to 60 months.

•	13 March 2014	Addition of pigs and horses as target species.
•	06 March 2014	Change of name of a finished product manufacturer, responsible for batch release.
•	07 December 2011	To change the shelf-life of the veterinary medicinal product from 24 to 36 months.
•	16 November 2011	To change the name of the manufacturer of the finished product.
•	01 July 2011	Repeat Use procedure.
•	08 April 2011	To submit a new updated European Pharmacopeia Certificate of Suitability for the active substance.
•	08 April 2011	To submit a new updated European Pharmacopeia Certificate of Suitability for the active substance.
•	25 November 2010	To submit a new updated European Pharmacopeia Certificate of Suitability for the active substance.
•	06 August 2010	To change the current aluminium cap to an equivalent flip-off aluminium cap.