Post Authorisation Assessments

Soliphen 60 mg Tablets for Dogs
Vm 54982/5006

•	11 May 2024	Introduce a new storage condition of the finished product, 'Do not store above 25°C'.
•	11 May 2024	Minor changes to an approved test procedure for an excipient.
•	11 May 2024	One-off alignment of the product information with version 9.0.
•	01 November 2023	Addition of new batch size.
•	04 March 2022	Change of MAH from Domes Pharma SC, 57 Rue des Bardines, 63370 Lempdes, France to Domes Pharma, 3 Rue Andre Citroen, 63430 Pont-du-Chateau, France.
•	03 February 2022	Introduction of a new pharmacovigilance system.
•	17 March 2021	Change in the name of the marketing authorisation holder from Laboratoire TVM to Domes Pharma SC.
•	27 November 2020	Introduction of a new pharmacovigilance system.
•	17 March 2020	Renewal – UK as CMS.
•	10 October 2019	Change in distributor details from TVM UK Animal Health Ltd, Crown House, 2-8 Gloucester Road, Redhill, RH1 1FH, United Kingdom to TVM UK Animal Health Ltd, Building B, Kirtlington Business Centre, Kirtlington, Oxfordshire OX5 3JA, United Kingdom.
•	02 July 2018	Change in the RMS from UK to DE.
•	25 April 2018	Change in distributor details. From Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS United Kingdom to TVM UK Animal Health Limited, Crown House, 2-8 Gloucester Road, Redhill, Surrey, RH1 1FH United Kingdom.
•	30 January 2018	Deletion of a manufacturing site for an active substance manufacturer.
•	28 November 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	15 August 2017	Deletion of a manufacturing site responsible for secondary packaging and batch control.
•	10 November 2016	Mock-ups Approved.
•	07 September 2016	Change of MAH, from Allifax to Laboratoire TVM. Change in distributor from Allifax, France to Dechra Veterinary Products Limited, United Kingdom.