



## Post Authorisation Assessments

### Prednicare Tablets 1mg Tablets

Vm 32742/4034

•	10 August 2023	Approval of mock ups.
•	11 August 2022	Change of MAH: from Animalcare Ltd, 10 Great North Way, York Business Park, Nether Poppleton, York, YO26 6RB, United Kingdom to Ecuphar NV, Legeweg 157-i, 8020 Oostkamp, Belgium.
•	16 April 2020	Updated label/leaflet and SPC to the current QRD template.
•	15 August 2019	Replacement of a manufacturer responsible for batch release including batch control/testing. Replacement of a secondary packaging site of the finished product. Replacement of a primary packaging site of the finished product. Deletion of manufacturing site for an active substance. Replacement of a manufacturing site of the finished product.
•	27 September 2018	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	26 February 2015	Change in distributor details.
•	16 January 2015	Submission of a new Ph. Eur. Certificate of Suitability for an active substance supplier.
•	21 June 2013	Variation to update the Marketing Authorisation Holder.
•	11 November 2008	Submission of a new or updated Certificate of Suitability.
•	30 September 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations 2005. Transfer of the legal category from POM to POM-V.
•	03 June 2008	Variation for submission of a new Certificate of Suitability.
•	04 April 2008	Batch Control.
•	16 December 2005	Renewal.
•	30 September 2003	Alternative manufacturer of Active Substance.
•	20 August 2003	Change in the name of the active substance manufacturer.
•	25 April 2003	Change of Release and Check specification of the finished product.
•	15 November 2002	Change of the finished product specification.

•	06 July 2000	Change of the finished product specification.
•	31 January 2000	Addition of a manufacturer and assembler of dosage form.
•	28 November 1999	Variation to update license particulars.
•	15 October 1999	Change to the dosage form manufacturer.
•	15 October 1999	Change to the dosage form manufacturer.
•	12 February 1998	Transfer (Renewal).