



Post Authorisation Assessments

Prednicare 5 mg Tablets

Vm 32742/4035

•	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's address.
•	11 November 2008	Submission of a new or updated European Pharmacopoeia Certificate of Suitability.
•	30 September 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	03 June 2008	Submission of a new European Pharmacopoeia Certificate of Suitability.
•	04 April 2008	Batch Control.
•	04 April 2008	Batch Control.
•	04 April 2008	Batch Control.
•	04 April 2008	Batch Control.
•	15 December 2005	Renewal.
•	30 September 2003	Addition of an alternative active substance manufacturer.
•	20 August 2003	Variation to change the name of the active substance

		manufacturer.
•	25 April 2003	Change of Release and Check specification for the finished product.
•	15 November 2002	Change to the finished product specification.
•	06 July 2000	Change to the finished product specification.
•	31 January 2000	Addition of a manufacturer and assembler of dosage form.
•	29 October 1999	Variation to update the licence particulars.
•	15 October 1999	Addition of a dosage form manufacturer.
•	10 February 1998	Transfer (Renewal).