



Post Authorisation Assessments

Isathal 10 mg/g Eye Drops, Suspension for Dogs, Cats and Rabbits Vm 24883/4003

•	12 April 2022	Pharmacovigilance related changes to SPC and product literature.
•	12 February 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	19 July 2017	Changes to the labelling and package leaflet
•	12 May 2017	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product
•	16 June 2014	Change in the invented name of the medicinal product from 'Fucithalamic Vet 10 mg/g Eye Drops, Suspension for Dogs, Cats and Rabbits' to 'Isathal 10 mg/g Eye Drops, Suspension for Dogs, Cats and Rabbits'.
•	19 September 2012	Submission of a new Ph. Eur. Certificate of Suitability for an active substance
•	07 December 2012	Change in packaging component
•	26 January 2011	Change of distributor
•	30 September 2010	Change of specification of an excipient
•	12 May 2010	Change of specification of the finished product
•	04 May 2010	Change in specification of the finished product
•	15 July 2009	Updates to Part II of the Dossier
•	21 April 2009	Change of composition of the immediate packaging
•	02 April 2009	Change of name of MAH
•	20 January 2009	Change of legal category from POM to POM-V Changes to the SPC and product Literature to bring in line with new legislation
•	11 September 2008	Change of design of the Product Literature
•	27 June 2008	Change of distributor
•	20 May 2008	Renewal
•	24 August 2006	Corrections to the Product Literature
•	01 August 2005	Change of MAH
•	30 June 2005	Change of distributor
•	14 January 2005	Change of colouring system of the packaging and layout of the product literature
•	27 January 2004	Renewal
•	09 August 2002	Change to product composition
•	29 December 2000	Change to specification of the active substance
•	30 March 1999	Addition of Rabbits to the target species
•	20 October 1998	Renewal

•	18 August 1997	Update to licence particulars
•	27 March 1997	Addition of Cats to the target species