



Post Authorisation Assessments

Galastop 50µg/ml Oral Solution Vm 28350/4001

•	24 June 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance.
•	13 December 2023	Change of MAH Address from Viale Colleoni 15, 20864 Agrate Brianza (MG), Italy to Ceva Salute Animale S.p.A, Via dei Valtorta 48, 20127 Milano, Italy.
•	20 October 2023	Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance.
•	07 November 2022	Change in distributor address from Unit 3 Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
•	16 May 2019	Submission of an updated Ph. Eur. certificate of suitability from an already approved manufacturer.
•	20 July 2016	Submission of an updated certificate of suitability. Submission of an updated certificate of suitability.
•	09 November 2011	Change of address of the distributor.
•	25 October 2011	Change of name and address of the MAH from Ceva Vetem S.p.A to Ceva Salute Anumale S.p.A.
•	08 April 2010	Change of name of a manufacturer of the active substance.
•	21 March 2009	Addition of a manufacturer of the active substance.
•	27 February 2008	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	23 June 2006	Change of MAH from Vetem Tecnica S.p.A to Ceva Vetem S.p.A.
•	31 January 2006	Renewal
•	24 March 2004	Change of MAH from Vetem to Vetem Tecnica S.p.A.
•	13 November 2002	Change of address of distributor
•	20 August 2001	Change of distributor
•	11 June 2001	Renewal
•	30 July 1999	Additional 3ml presentation
•	16 March 1998	Change of distributor