

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS Telephone +44 (0)1932 336911

Post Authorisation Assessments

Sodium Calciumedetate 250 mg/ml Concentrate for solution for injection

•	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.
•	04 June 2013	Variation to update the Marketing Authorisation Holder address.
•	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.
•	07 July 2008	Renewal.
•	02 March 2005	Renewal.
•	24 July 2001	Addition of a manufacturer and assembler of dosage form.
•	27 October 1998	Renewal.
•	06 January 1998	Change of name of the Marketing Authorisation Holder.