



Post Authorisation Assessments

Equidronate 500 mg Lyophilisate for Solution for Infusion Vm 44684/4000

•	22 September 2022	Replacement or addition of a site where batch control/testing takes place.
•	03 March 2022	Change in the address of the marketing authorisation holder from AUDEVARD, 42-46 rue Médéric 92110, Clichy, France to AUDEVARD, 37-39 rue de Neuilly, 92110 Clichy, France. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	22 September 2020	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS. Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	18 June 2019	Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	21 December 2016	Change in distributor details. From Ceva Animal Health Ltd to AUDEVARD.
•	16 December 2016	Introduction of a new pharmacovigilance system.
•	18 October 2016	Change of Marketing Authorisation holder from Ceva Animal Health Ltd to AUDEVARD.
•	16 December 2015	Changes to Update the DDPS.
•	19 February 2014	Renewal.
•	11 October 2013	Changes to an existing pharmacovigilance system.
•	23 September 2011	To change the address of the Marketing Authorisation Holder.
•	27 June 2011	To update the indications for use.