



Post Authorisation Assessments

Fixplan 200 IU/ml Lyophilisate and Solvent for Solution for Injection Vm 54400/4001

•	27 April 2022	Repeat use to add 4 new CMS.
•	22 December 2021	Approval of mock-ups.
•	09 December 2021	Replacement of a manufacturer responsible for importation / batch release of the finished product. Replacement of a site where batch control/testing takes place.
•	20 October 2021	Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	11 June 2021	Change in the name and address of the Marketing Authorisation Holder from Cyton AH Biosciences GmbH, Konrad-Zuse-Ring 25, 68163 Mannheim, Germany to Syn Vet-Pharma Ireland Limited, Business Service Group, 7A Durands Court, 45 Parnell Street, Waterford X91 P381, Ireland.