



Post Authorisation Assessments

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

15 January 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (GB).
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.