



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 December 2023
EMA/CHMP/549864/2023
Human Medicines Division

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product

Filsuvez/ birch bark extract

common name

Pharmaceutical form(s): See Annex A of the CHMP Opinion

Strength(s): See Annex A

Route(s) of administration: See Annex A

Packaging and package size(s): See Annex A

Number(s) in the Community Register of Medicinal Products: See Annex A

Marketing Authorisation Holder (MAH):

Name and address of the MAH: Amryt Pharmaceuticals DAC
45 Mespil Road
Ballsbridge
Dublin 4
Co. Dublin
D04 W2F1
IRELAND

Procedure

Procedure number: EMEA/H/C/005035/II/0006

Further to the compliance check performed under Article 23 of Regulation (EC) No 1901/2006, and in accordance with Article 28(3) and Article 45(3) of the said Regulation it is concluded that:

-the development of this product has complied with all measures in the agreed paediatric investigation plan P/0541/2023. All studies in the agreed paediatric investigation plan P/0541/2023 were conducted after the entry into force of that Regulation,

-the Summary of Product Characteristics reflects the results of studies conducted in compliance with this agreed paediatric investigation plan.



In accordance with Article 23a of Regulation (EC) No 1234/2008, this statement indicating compliance with the agreed completed paediatric investigation plan P/0541/2023 is included in the technical dossier.