



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 June 2024
EMA/CHMP/298354/2024
Human Medicines Division

Statement indicating compliance with the agreed completed paediatric investigation plan

Medicinal product

Cresemba/ isavuconazole

Pharmaceutical forms: See Annex A of the CHMP Opinion

Strengths: See Annex A

Routes of administration: See Annex A

Packaging and package sizes: See Annex A

Numbers in the Community See Annex A

Register of Medicinal Products:

Marketing Authorisation Holder (MAH):

Name and address of the MAH: Basilea Pharmaceutica Deutschland GmbH
Marie-Curie-Strasse 8
79539 Lorrach
GERMANY

Procedure

Procedure number: EMEA/H/C/002734/X/0042/G

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/0479/2021. All studies in the agreed paediatric investigation plan P/0479/2021 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/0479/2021 is included in the technical dossier.

