



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-1809722

European Medicines Agency decision

EMA/PE/0000225241

of 3 January 2025

on the agreement of a paediatric investigation plan and on the granting of a deferral for calcium chloride dihydrate, d-glucose, levocarnitine, magnesium chloride hexahydrate, sodium chloride, sodium lactate, xylitol (XyloCore) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.



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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004¹,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency²,

Having regard to the application submitted by Iperboreal Pharma S.r.l. on 12 August 2024 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 November 2024, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

- (1) The Paediatric Committee of the European Medicines Agency has given an opinion on the on the agreement of a paediatric investigation plan and on the granting of a deferral.
- (2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision granting a deferral.

¹ OJ L 378, 27.12.2006, p.1, as amended.

² OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

A paediatric investigation for calcium chloride dihydrate, d-glucose, levocarnitine, magnesium chloride hexahydrate, sodium chloride, sodium lactate, xylitol (XyloCore), the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for calcium chloride dihydrate, d-glucose, levocarnitine, magnesium chloride hexahydrate, sodium chloride, sodium lactate, xylitol (XyloCore), the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Iperboreal Pharma S.r.l., Via L' Aquila 9, 65121 - Pescara, Italy.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-1724310
Amsterdam, 15 November 2024

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMA/PE/0000225241

Scope of the application

Active substance(s):

Calcium chloride dihydrate, d-glucose, levocarnitine, magnesium chloride hexahydrate, sodium chloride, sodium lactate, xylitol (XyloCore)

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of renal failure

Pharmaceutical form(s):

Solution for peritoneal dialysis

Route(s) of administration:

Intraperitoneal use

Name/corporate name of the PIP applicant:

Iperboreal Pharma S.r.l.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Iperboreal Pharma S.r.l. submitted for agreement to the European Medicines Agency on 12 August 2024 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 16 September 2024.



Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
- to grant a deferral in accordance with Article 21 of said Regulation.

The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

Not applicable

2. Paediatric investigation plan

2.1. Condition:

Treatment of renal failure

2.1.1. Indication(s) targeted by the PIP

Treatment of renal failure of any origin in paediatric patients of all ages which can be treated with peritoneal dialysis

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for peritoneal dialysis

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	Study 1: Open-label, uncontrolled trial to evaluate safety and efficacy of XyloCore solution for peritoneal dialysis (PD) in children from birth to less than 18 years of age with end stage renal disease (ESRD) receiving peritoneal dialysis (IP-001-24)
Modelling and simulation analyses	Not applicable
Other studies	Not applicable
Extrapolation plan	Study 1 (IP-001-24) is part of an extrapolation plan covering the paediatric population from birth to less than 18 years of age, as agreed by the PDCO.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By May 2030
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.