EMA/379809/2018

European Medicines Agency decision

P/0196/2018

of 17 July 2018

on the acceptance of a modification of an agreed paediatric investigation plan for sucroferric oxyhydroxide (mixture of iron (III)-oxyhydroxide, sucrose, starch) (PA21) (EMEA-001061-PIP01-10-M03) 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 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/284/2011 issued on 30 November 2011, the decision P/0087/2014 issued on 4 April 2014 and the decision P/0205/2015 issued on 4 September 2015,

Having regard to the application submitted by Vifor Fresenius Medical Care Renal Pharma France on 12 March 2018 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 1 June 2018, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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 acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for sucroferric oxyhydroxide (mixture of iron (III)-oxyhydroxide, sucrose, starch) (PA21), powder for oral suspension, chewable tablet, oral use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Vifor Fresenius Medical Care Renal Pharma France, 100-101 Terrasse, Boieldieu Tour Franklin La Défense 8, F-92042 - Paris La Défense Cedex, France.

EMA/PDCO/173555/2018
London, 1 June 2018

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-001061-PIP01-10-M03

Scope of the application

Active substance(s):

Sucroferric oxyhydroxide (mixture of iron (III)-oxyhydroxide, sucrose, starch) (PA21)

Invented name:

Velphoro

Condition(s):

Treatment of hyperphosphataemia

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for oral suspension

Chewable tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Vifor Fresenius Medical Care Renal Pharma France

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Vifor Fresenius Medical Care Renal Pharma France submitted to the European Medicines Agency on 12 March 2018 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/284/2011 issued on 30 November 2011, the decision P/0087/2014 issued on 4 April 2014 and the decision P/0205/2015 issued on 4 September 2015.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 3 April 2018.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

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

2. The measures and timelines of the 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 hyperphosphataemia

2.1.1. Indication(s) targeted by the PIP

Treatment of hyperphosphataemia in patients with chronic kidney disease

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)

Powder for oral suspension

Chewable tablets

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	1	**Study 1** Development of a powder for oral suspension
Non-clinical studies	0	Not applicable.
Clinical studies	1	**Study 2** Open-label, randomised, multicentre, active-controlled parallel group trial to evaluate efficacy and safety of PA21 in children from birth to less than 18 years of age with hyperphosphataemia in chronic kidney disease, with a 24-week open-label extension to evaluate safety
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By August 2019
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s)

1. Treatment of hyperphosphataemia

Authorised indication(s):

- Velphoro is indicated for the control of serum phosphorus levels in adult chronic kidney disease (CKD) patients on haemodialysis (HD) or peritoneal dialysis (PD).

Authorised pharmaceutical form(s)

Chewable tablet

Authorised route(s) of administration

Oral use