

EMA/247030/2011

European Medicines Agency decision

P/103/2011

of 3 May 2011

on the acceptance of a modification of an agreed paediatric investigation plan for conestat alfa (Ruconest) (EMA-000367-PIP01-08-M01) 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency²,

Having regard to the European Medicines Agency's decision P/132/2009 issued on 17 July 2009,

Having regard to the application submitted by Pharming Group N.V. on 23 December 2010 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 March 2011, 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 conestat alfa (Ruconest), powder for solution for injection, intravenous 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 Pharming Group N.V., Darwinweg 24, 2333 CR Leiden, The Netherlands.

Done at London, 3 May 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/98361/2011

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

EMA-000367-PIP01-08-M01

Scope of the application

Active substance(s):

Conestat alfa

Invented name:

Ruconest

Condition(s):

Hereditary angioedema

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for solution for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Pharming Group N.V.

Information about the authorised medicinal product:

See Annex II



Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Pharming Group N.V. submitted to the European Medicines Agency on 23 December 2010 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/132/2009 issued on 17 July 2009.

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

The procedure started on 19 January 2011.

Scope of the modification

Some measures and timelines of the original Opinion have been modified.

Opinion

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 Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

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

London, 18 March 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

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

1. Waiver

1.1. Condition: Hereditary angioedema

The waiver applies to:

- The paediatric population from birth to less than 2 years of age for powder for solution for injection, intravenous use, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

2. Paediatric Investigation Plan

2.1. Condition: Hereditary angioedema

2.1.1. Indication(s) targeted by the PIP

Treatment of acute attacks of angioedema associated with hereditary C1 esterase inhibitor deficiency.

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

From 2 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder for solution for injection, 2100 U

2.1.4. Studies

Area	Number of studies	Description
Quality	N.A.	Not applicable
Non-clinical	N.A.	Not applicable.
Clinical	2	Study 1 Open-label, single arm trial to evaluate the safety and immunogenicity of conestat alfa for the treatment of acute attacks in adolescents (and adults) with hereditary angioedema from 14 to less than 18 years old. Study 2 Open label, single-arm trial to evaluate the safety and immunogenicity of conestat alfa for the treatment of acute attacks in children with hereditary angioedema from 2 to 14 years of age.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2012
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):

Treatment of Hereditary angioedema

Authorised indications:

Treatment of acute angioedema attacks in adults with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency

EU Number	Invented name	Strength	Pharmaceutical form	Route of administration	Packaging	Content (concentration)	Package size
EU/1/10/641/001	Ruconest	2100 IU	Powder for solution for injection	Intravenous use	vial (glass)		1 vial