



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/702366/2015

European Medicines Agency decision

P/0263/2015

of 30 October 2015

on the refusal of a modification of an agreed paediatric investigation plan for rufinamide (Inovelon) (EMA-000709-PIP01-09-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 726/2004¹,

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/153/2010 issued on 27 August 2010, the decision P/0275/2013 issued on 30 October 2013 and the decision P/0277/2014 issued on 28 October 2014,

Having regard to the application submitted by Eisai Limited on 20 July 2015 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 9 October 2015, 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 refusal of changes to the agreed paediatric investigation plan.
- (2) It is therefore appropriate to adopt a decision on the refusal 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 rufinamide (Inovelon), tablet, oral suspension, oral use, 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, are hereby refused.

Article 2

This decision is addressed to Eisai Limited, European Knowledge Centre, Mosquito Way, AL10 9SN Hatfield, Hertfordshire, United Kingdom.

Done at London, 30 October 2015

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/499940/2015
London, 9 October 2015

Opinion of the Paediatric Committee on the refusal of a modification of an agreed Paediatric Investigation Plan EMA-000709-PIP01-09-M03

Scope of the application

Active substance(s):

Rufinamide

Invented name:

Inovelon

Condition(s):

Treatment of Lennox-Gastaut Syndrome

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Tablet

Oral suspension

Route(s) of administration:

Oral use

Name / corporate name of the PIP applicant:

Eisai Limited

Information about the authorised medicinal product:

See Annex II



Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Eisai Limited submitted to the European Medicines Agency on 20 July 2015 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/153/2010 issued on 27 August 2010, the decision P/0275/2013 issued on 30 October 2013 and the decision P/0277/2014 issued on 28 October 2014.

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

The procedure started on 11 August 2015.

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 refuse the changes proposed by the applicant regarding the paediatric investigation plan.

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

2. The measures and timelines of the agreed paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver remain unchanged and are set out in the Annex I.
3. The scientific conclusions and the grounds for refusal are set out in the summary report appended to this opinion.

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

1.1. Condition(s)

Treatment of Lennox-Gastaut syndrome

The waiver applies to:

- all subsets of the paediatric population from birth to less than 12 months of age;
- for oral suspension, oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s);

and to:

- all subsets of the paediatric population from 4 to less than 18 years of age;
- for oral suspension and tablets, oral use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

2. Paediatric Investigation Plan

2.1. Condition

Treatment of Lennox-Gastaut syndrome

2.1.1. Indication(s) targeted by the PIP

Adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome

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

From 1 to less than 4 years of age

2.1.3. Pharmaceutical form(s)

Oral suspension

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1 Palatability and acceptability assessment of the oral suspension in children with Lennox-Gastaut syndrome

Non-clinical studies	1	Study 2 13-week oral toxicity Study in juvenile dogs
Clinical studies	1	Study 3 Multicentre, randomised, controlled, open-label study to evaluate the effect on cognitive development, safety, and pharmacokinetics of adjunctive rufinamide treatment in paediatric subjects 1 to less than 4 years of age with inadequately controlled Lennox-Gastaut syndrome

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues and efficacy in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By September 2017
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 Lennox-Gastaut Syndrome

Authorised indication(s):

- adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome in patients 4 years of age and older

Authorised pharmaceutical form(s)

Film-coated tablet, oral suspension

Authorised route(s) of administration

Oral route