



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/472452/2012

European Medicines Agency decision P/0188/2012

of 21 August 2012

on the granting of a product specific waiver for amlodipine (besilate) / lisinopril (dihydrate) / rosuvastatin (calcium), (EMA-001291-PIP01-12) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 application submitted by Gedeon Richter Plc. on 10 April 2012 under Article 13 of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 6 July 2012 in accordance with Article 13 of Regulation (EC) No 1901/2006,

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

Whereas:

- (1) The Paediatric Committee has given an opinion on the granting of a product specific waiver.
- (2) It is therefore appropriate to adopt a decision granting a waiver.

¹ OJ L 378, 27.12.2006, p.1.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A waiver for amlodipine (besilate) / lisinopril (dihydrate) / rosuvastatin (calcium), capsule, hard, 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, is hereby granted.

Article 2

This decision is addressed to Gedeon Richter Plc., Gyömrői út 19-21., 1103 – Budapest, Hungary.

Done at London, 21 August 2012

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)



EUROPEAN MEDICINES AGENCY
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EMA/PDCO/285973/2012

Opinion of the Paediatric Committee on the granting of a product-specific waiver

EMA-001291-PIP01-12

Scope of the application

Active substance(s):

Amlodipine (besilate) / lisinopril (dihydrate) / rosuvastatin (calcium)

Condition(s):

Treatment of heart failures

Treatment of ischemic coronary artery disorders

Cardiovascular event prophylaxis

Treatment of dyslipidaemia

Treatment of elevated cholesterol

Treatment of vascular hypertensive disorders

Pharmaceutical form(s):

Capsule, hard

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Gedeon Richter Plc.



Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Gedeon Richter Plc. submitted to the European Medicines Agency on 10 April 2012 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

The procedure started on 15 May 2012.

Opinion

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to grant a product-specific waiver for all subsets of the paediatric population and all the above mentioned condition(s) in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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

2. The grounds for the granting of the waiver are set out in Annex I.

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

Langen, Germany, 6 July 2012

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

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition: Treatment of heart failures

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- For capsule, hard for oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.2. Condition: Treatment of ischemic coronary artery disorders

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- For capsule, hard for oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.3. Condition: Cardiovascular event prophylaxis

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- For capsule, hard for oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.4. Condition: Treatment of dyslipidaemia

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- For capsule, hard for oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.5. Condition: Treatment of elevated cholesterol

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- For capsule, hard for oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.6. Condition: Treatment of vascular hypertensive disorders

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- For capsule, hard for oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.