EMA/170473/2011

European Medicines Agency decision

P/65/2011

of 11 March 2011

on the granting of a product specific waiver for rivastigmine, (EMEA-001084-PIP01-10) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Only the English text is authentic.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8670
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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on the granting of a product specific waiver for rivastigmine, (EMEA-001084-PIP01-10) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 application submitted by Novartis Europharm Ltd. on 15 November 2010 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 18 February 2011 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 rivastigmine, transdermal patch, transdermal 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 Novartis Europharm Ltd., Wimblehurst Road, Horsham, West Sussex RH12 5AB, United-Kingdom.

Done at London, 11 March 2011

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

EMA/PDCO/53433/2011

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

EMEA-001084-PIP01-10

Scope of the application

Active substance(s):

Rivastigmine

Invented name:

Exelon and Prometax

Condition(s):

Treatment of dementia

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Transdermal patch

Route(s) of administration:

Transdermal use

Name/corporate name of the PIP applicant:

Novartis Europharm Ltd.

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Ltd. submitted to the European Medicines Agency on 15 November 2010 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 22 December 2010.

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 the above mentioned condition(s) in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended occurs only in adult populations.

   The Icelandic and the Norwegian Paediatric Committee members agree 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.

London, 18 February 2011

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 dementia

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age,
- for transdermal patch, transdermal use,
- on the grounds that the disease or condition for which the specific medicinal product is intended only occurs in adults.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of dementia

   Authorised indications: Symptomatic treatment of mild to moderately severe dementia in patients with idiopathic Parkinson's disease

2. Treatment of Alzheimer's disease

   Authorised indications: Symptomatic treatment of mild to moderately severe Alzheimer's dementia.

EU Number	**Invented name**	**Strength**	**Pharma-ceutical Form**	**Route of Administration**	**Packaging**	**Package size**
EU/1/98/066/019	Exelon	4.6 mg/24 h	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)	7 sachets
EU/1/98/066/020	Exelon	4.6 mg/24 h	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)	30 sachets
EU/1/98/066/021	Exelon	4.6 mg/24 h	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)	60 sachets (30x2 sachets)
EU/1/98/066/022	Exelon	4.6 mg/24 h	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)	90 sachets (30x3 sachets)
EU/1/98/066/023	Exelon	9.5 mg/24 h	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)	7 sachets
EU/1/98/066/024	Exelon	9.5 mg/24 h	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)	30 sachets
EU/1/98/066/025	Exelon	9.5 mg/24 h	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)	60 sachets (30x2 sachets)
EU/1/98/066/026	Exelon	9.5 mg/24 h	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)	90 sachets (30x3 sachets)
EU/1/98/092/019	Prometax	4.6 mg/24 h	Transdermal patch	Transdermal use	Sachet (paper/polyester/alu/pol	7 sachets

					yacrylonitrile)	
EU/1/98/092/020	Prometax	4.6 mg/24 h	Transdermal patch	Transdermal use	Sachet (paper/polyester/alu/polyacrylonitrile)	30 sachets
EU/1/98/092/021	Prometax	4.6 mg/24 h	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)	60 sachets (30x2 sachets)
EU/1/98/092/022	Prometax	4.6 mg/24 h	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)	90 sachets (30x3 sachets)
EU/1/98/092/023	Prometax	9.5 mg/24 h	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)	7 sachets
EU/1/98/092/024	Prometax	9.5 mg/24 h	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)	30 sachets
EU/1/98/092/025	Prometax	9.5 mg/24 h	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)	60 sachets (30x2 sachets)
EU/1/98/092/026	Prometax	9.5 mg/24 h	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)	90 sachets(30x3 sachets)