EMA/320397/2011

European Medicines Agency decision

P/113/2011

of 27 April 2011

on the granting of a product specific waiver for rivastigmine (Exelon and Prometax) (EMEA-001084-PIP02-11) 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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on the granting of a product specific waiver for rivastigmine (Exelon and Prometax) (EMEA-001084-PIP02-11) 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 14 March 2011 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 20 April 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 (Exelon and Prometax), hard capsules, oral solution, transdermal patch, oral use, 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, West Sussex, RH12 5AB Horsham - London, United Kingdom.

Done at London, 27 April 2011

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

EMA/PDCO/316027/2011

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

EMEA-001084-PIP02-11

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):

Hard Capsules

Oral Solution

Transdermal patch

Route(s) of administration:

Oral use

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 14 March 2011 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 18 April 2011.

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 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.

London, 20 April 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 hard capsules, oral solution, transdermal patch, oral use and 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	Content (concentration)	Package size
EU/1/98/066/001	Exelon	1.5 mg	Capsule, hard	Oral use	blister (PVC/alu)		28 capsules
EU/1/98/066/002	Exelon	1.5 mg	Capsule, hard	Oral use	blister (PVC/alu)		56 capsules
EU/1/98/066/003	Exelon	1.5 mg	Capsule, hard	Oral use	blister (PVC/alu)		112 capsules
EU/1/98/066/004	Exelon	3 mg	Capsule, hard	Oral use	blister (PVC/alu)		28 capsules
EU/1/98/066/005	Exelon	3 mg	Capsule, hard	Oral use	blister (PVC/alu)		56 capsules
EU/1/98/066/006	Exelon	3 mg	Capsule, hard	Oral use	blister (PVC/alu)		112 capsules
EU/1/98/066/007	Exelon	4.5 mg	Capsule, hard	Oral use	blister (PVC/alu)		28 capsules
EU/1/98/066/008	Exelon	4.5 mg	Capsule, hard	Oral use	blister (PVC/alu)		56 capsules
EU/1/98/066/009	Exelon	4.5 mg	Capsule, hard	Oral use	blister (PVC/alu)		112 capsules
EU/1/98/066/010	Exelon	6 mg	Capsule, hard	Oral use	blister (PVC/alu)		28 capsules
EU/1/98/066/011	Exelon	6 mg	Capsule, hard	Oral use	blister (PVC/alu)		56 capsules
EU/1/98/066/012	Exelon	6 mg	Capsule, hard	Oral use	blister (PVC/alu)		112 capsules
EU/1/9	Exelon	2	Oral	Oral use	bottle	120 ml	1 bottle

EU Number	(Invented) name	Strength	Pharma-ceutical Form	Route of Administration	Packaging	Content (concentration)	Package size
8/066/013		mg/ml	solution		(amber glass)		
EU/1/98/066/014	Exelon	1.5 mg	Capsule, hard	Oral use	bottle (HDPE)		250 capsules
EU/1/98/066/015	Exelon	3 mg	Capsule, hard	Oral use	bottle (HDPE)		250 capsules
EU/1/98/066/016	Exelon	4.5 mg	Capsule, hard	Oral use	bottle (HDPE)		250 capsules
EU/1/98/066/017	Exelon	6 mg	Capsule, hard	Oral use	bottle (HDPE)		250 capsules
EU/1/98/066/018	Exelon	2 mg/ml	Oral solution	Oral use	bottle (amber glass)	50 ml	1 bottle
EU/1/98/066/019	Exelon	4.6 mg / 24 hours	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)		7 sachets
EU/1/98/066/020	Exelon	4.6 mg / 24 hours	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)		30 sachets
EU/1/98/066/021	Exelon	4.6 mg / 24 hours	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)		60 (30 x 2) sachets
EU/1/98/066/022	Exelon	4.6 mg / 24 hours	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)		90 (30 x 3) sachets
EU/1/98/066/023	Exelon	9.5 mg / 24 hours	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)		7 sachets
EU/1/98/066/024	Exelon	9.5 mg / 24 hours	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylon		30 sachets

EU Number	(Invented) name	Strength	Pharma-ceutical Form	Route of Administration	Packaging	Content (concentration)	Package size
					itrile)		
EU/1/98/066/025	Exelon	9.5 mg / 24 hours	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)		60 sachets (30 x 2 sachets)
EU/1/98/066/026	Exelon	9.5 mg / 24 hours	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)		90 sachets (30 x 3 sachets)

EU Number	(Invented) name	Strength	Pharma-ceutical Form	Route of Administration	Packaging	Content (concentration)	Package size
EU/1/98/092/001	Prometax	1.5 mg	Capsule, hard	Oral use	blister (PVC/alu)		28 capsules
EU/1/98/092/002	Prometax	1.5 mg	Capsule, hard	Oral use	blister (PVC/alu)		56 capsules
EU/1/98/092/003	Prometax	1.5 mg	Capsule, hard	Oral use	blister (PVC/alu)		112 capsules
EU/1/98/092/004	Prometax	3 mg	Capsule, hard	Oral use	blister (PVC/alu)		28 capsules
EU/1/98/092/005	Prometax	3 mg	Capsule, hard	Oral use	blister (PVC/alu)		56 capsules
EU/1/98/092/006	Prometax	3 mg	Capsule, hard	Oral use	blister (PVC/alu)		112 capsules
EU/1/98/092/007	Prometax	4.5 mg	Capsule, hard	Oral use	blister (PVC/alu)		28 capsules
EU/1/98/092/008	Prometax	4.5 mg	Capsule, hard	Oral use	blister (PVC/alu)		56 capsules
EU/1/98/092/009	Prometax	4.5 mg	Capsule, hard	Oral use	blister (PVC/alu)		112 capsules
EU/1/98/092/010	Prometax	6 mg	Capsule, hard	Oral use	blister (PVC/alu)		28 capsules

EU Number	(Invented) name	Strength	Pharma-ceutical Form	Route of Administration	Packaging	Content (concentration)	Package size
EU/1/98/092/011	Prometax	6 mg	Capsule, hard	Oral use	blister (PVC/alu)		56 capsules
EU/1/98/092/012	Prometax	6 mg	Capsule, hard	Oral use	blister (PVC/alu)		112 capsules
EU/1/98/092/013	Prometax	2 mg/ml	Oral solution	Oral use	bottle (amber glass)	120 ml	1 bottle
EU/1/98/092/014	Prometax	1.5 mg	Capsule, hard	Oral use	bottle (HDPE)		250 capsules
EU/1/98/092/015	Prometax	3 mg	Capsule, hard	Oral use	bottle (HDPE)		250 capsules
EU/1/98/092/016	Prometax	4.5 mg	Capsule, hard	Oral use	bottle (HDPE)		250 capsules
EU/1/98/092/017	Prometax	6 mg	Capsule, hard	Oral use	bottle (HDPE)		250 capsules
EU/1/98/092/018	Prometax	2 mg/ml	Oral solution	Oral use	bottle (amber glass)	50 ml	1 bottle
EU/1/98/092/019	Prometax	4.6 mg / 24 hours	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)		7 sachets
EU/1/98/092/020	Prometax	4.6 mg / 24 hours	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)		30 sachets
EU/1/98/092/021	Prometax	4.6 mg / 24 hours	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)		60 (30 x 2) sachets
EU/1/98/092/022	Prometax	4.6 mg / 24 hours	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)		90 (30 x 3) sachets
EU/1/9	Prometax	9.5 mg	Transde	Transdermal	sachet		7 sachets

EU Number	(Invented) name	Strength	Pharma-ceutical Form	Route of Administration	Packaging	Content (concentration)	Package size
8/092/023		/ 24 hours	rmal patch	use	(paper/polyester/alu/polyacrylonitrile)		
EU/1/98/092/024	Prometax	9.5 mg / 24 hours	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)		30 sachets
EU/1/98/092/025	Prometax	9.5 mg / 24 hours	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)		60 (30 x 2) sachets
EU/1/98/092/026	Prometax	9.5 mg / 24 hours	Transdermal patch	Transdermal use	sachet (paper/polyester/alu/polyacrylonitrile)		90 (30 x 3) sachets