EMA/477373/2010

European Medicines Agency decision

P/159/2010

of 27/08/2010

on the granting of a product specific waiver for telmisartan / hydrochlorothiazide (MicardisPlus), (EMEA-000885-PIP01-10) 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 726/2004[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 Boehringer Ingelheim International GmbH on 12 April 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 16 July 2010 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 telmisartan / hydrochlorothiazide (MicardisPlus), tablet, 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 Boehringer Ingelheim International GmbH, Binger Str 173, 55216 Ingelheim am Rhein, Germany.

Done at London, 27 August 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/410115/2010

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

EMEA-000885-PIP01-10

Scope of the application

Active substance(s):

Telmisartan

Hydrochlorothiazide

Invented name:

MicardisPlus

Condition(s):

Hypertension

Pharmaceutical form(s):

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Boehringer Ingelheim International GmbH

Information about the authorised medicinal product: see Annex II

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Boehringer Ingelheim International GmbH submitted to the European Medicines Agency on 12 April 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 20 May 2010.

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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)(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.

London, 16 July 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

Grounds for the granting of the waiver

1. GROUNDS FOR THE GRANTING OF THE WAIVER

1.1. Condition

Hypertension

The waiver applies to:

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

Annex II

Information about the authorised medicinal product

EU Number	Invented name	Strength	Pharmaceutical form	Route of administration	Packaging	Package size
EU/1/02/213/001	MicardisPlus	40 mg/12.5 mg	Tablet	Oral use	blister (polyamide/alu/PVC)	14 tablets
EU/1/02/213/002	MicardisPlus	40 mg/12.5 mg	Tablet	Oral use	blister (polyamide/alu/PVC)	28 tablets
EU/1/02/213/003	MicardisPlus	40 mg/12.5 mg	Tablet	Oral use	blister (polyamide/alu/PVC)	28 x 1 tablets
EU/1/02/213/004	MicardisPlus	40 mg/12.5 mg	Tablet	Oral use	blister (polyamide/alu/PVC)	56 tablets
EU/1/02/213/005	MicardisPlus	40 mg/12.5 mg	Tablet	Oral use	blister (polyamide/alu/PVC)	98 tablets
EU/1/02/213/006	MicardisPlus	80 mg/12.5 mg	Tablet	Oral use	blister (polyamide/alu/PVC)	14 tablets
EU/1/02/213/007	MicardisPlus	80 mg/12.5 mg	Tablet	Oral use	blister (polyamide/alu/PVC)	28 tablets
EU/1/02/213/008	MicardisPlus	80 mg/12.5 mg	Tablet	Oral use	blister (polyamide/alu/PVC)	28 x 1 tablets
EU/1/02/213/009	MicardisPlus	80 mg/12.5 mg	Tablet	Oral use	blister (polyamide/alu/PVC)	56 tablets
EU/1/02/213/010	MicardisPlus	80 mg/12.5 mg	Tablet	Oral use	blister (polyamide/alu/PVC)	98 tablets
EU/1/02/213/011	MicardisPlus	40 mg/12.5 mg	Tablet	Oral use	blister (polyamide/alu/PVC)	84 tablets
EU/1/02/213/012	MicardisPlus	80 mg/12.5 mg	Tablet	Oral use	blister (polyamide/alu/PVC)	84 tablets
EU/1/02/213/013	MicardisPlus	40 mg/12.5 mg	Tablet	Oral use	blister (polyamide/alu/PVC)	30 x 1 tablet
EU/1/02/213/014	MicardisPlus	40 mg/12.5 mg	Tablet	Oral use	blister (polyamide/alu/PVC)	90 x 1 tablet
EU/1/02/213/015	MicardisPlus	80 mg/12.5 mg	Tablet	Oral use	blister (polyamide/alu/PVC)	30 x 1 tablet
EU/1/02/213/016	MicardisPlus	80 mg/12.5 mg	Tablet	Oral use	blister (polyamide/alu/PVC)	90 x 1 tablet
EU/1/02/213/017	MicardisPlus	80 mg/25 mg	Tablet	Oral use	blister (PA/alu/PVC)	14 tablets
EU/1/02/213/018	MicardisPlus	80 mg/25 mg	Tablet	Oral use	blister (PA/alu/PVC)	28 tablets
EU/1/02/213/019	MicardisPlus	80 mg/25 mg	Tablet	Oral use	blister (PA/alu/PVC)	28 x 1 tablets
EU/1/02/213/020	MicardisPlus	80 mg/25 mg	Tablet	Oral use	blister (PA/alu/PVC)	30 x 1 tablet
EU/1/02/213/021	MicardisPlus	80 mg/25 mg	Tablet	Oral use	blister (PA/alu/PVC)	56 tablets
EU/1/02/	MicardisPl	80 mg/25	Tablet	Oral use	blister	90 x 1

EU Number	Invented name	Strength	Pharmaceutical form	Route of administration	Packaging	Package size
213/022	us	mg			(PA/alu/PVC)	tablet
EU/1/02/ 213/023	MicardisPl us	80 mg/25 mg	Tablet	Oral use	blister (PA/alu/PVC)	98 tablets