EMA/477499/2010

European Medicines Agency decision

P/169/2010

of 3 September 2010

on the granting of a product specific waiver for vildagliptin / metformin hydrochloride (Eucreas), (EMEA-000703-PIP01-09) 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 Novartis Europharm Limited on 10 September 2009 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 vildagliptin / metformin hydrochloride (Eucreas), film-coated 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 Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex RH12 5AB, United-Kingdom.

Done at London, 3 September 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/423554/2010

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

EMEA-000703-PIP01-09

Scope of the application

Active substance(s):

Vildagliptin / metformin hydrochloride

Invented name:

Eucreas

Condition(s):

Type 2 diabetes mellitus

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Novartis Europharm Limited

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Limited submitted to the European Medicines Agency on 10 September 2009 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 October 2009.

Supplementary information was provided by the applicant on 28 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

Type 2 diabetes mellitus

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- For film coated tablets 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

Invented name Name	Strength	Pharmaceutical form	Route of administration
Eucreas	50mg /850mg 50mg /1000mg	Film-coated Tablets	Oral use
Icandra	50mg /850mg 50mg /1000mg	Film-coated Tablets	Oral use
Zomarist	50mg /850mg 50mg /1000mg	Film-coated Tablets	Oral use