European Medicines Agency

Doc. Ref. EMA/116975/2010
P/26/2010

EUROPEAN MEDICINES AGENCY DECISION

of 3 March 2010

on the acceptance of a modification of an agreed Paediatric Investigation Plan for nevirapine (Viramune) (EMEA-000391-PIP01-08-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 decision P/134/2009 of the European Medicines Agency on 15 July 2009,

Having regard to the application submitted by Boehringer Ingelheim International GmbH on 4 December 2009 under Article 22 of Regulation (EC) No 1901/2006 as amended proposing changes to the agreed Paediatric Investigation Plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 January 2010, in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended,

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

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to an agreed Paediatric Investigation Plan.

(2) It is therefore appropriate to adopt a Decision on the acceptance of changes to an agreed Paediatric Investigation Plan.

[1] OJ L 378, 27.12.2006, p.1
[2] OJ L 136, 30.4.2004, p. 1

HAS ADOPTED THIS DECISION:

Article 1

Changes to the agreed Paediatric Investigation Plan for nevirapine (Viramune), Prolonged release tablet, tablet and oral suspension, 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, are hereby accepted.

Article 2

This decision is addressed to Boehringer Ingelheim International GmbH, Binger Straße 173, 55216 Ingelheim am Rhein, Germany.

Done at London, 3 March 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMA/PDCO/826695/2009
EMA-000391-PIP01-08-M01

OPINION OF THE PAEDIATRIC COMMITTEE ON THE ACCEPTANCE OF A MODIFICATION OF AN AGREED PAEDIATRIC INVESTIGATION PLAN

Scope of the application

Active substance(s):
Nevirapine

(Invented) name:
Viramune

Condition(s):
Human immunodeficiency virus (HIV-1) infection

Pharmaceutical form(s):
Prolonged release tablet
Tablet
Oral suspension

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 22 of Regulation (EC) No 1901/2006 as amended, Boehringer Ingelheim International GmbH submitted to the Agency on 4 December 2009 an application for modification of the agreed paediatric investigation plan as set out in the Agency's decision P/134/2009 of 15 July 2009. The application for modification proposed changes.

The procedure started on 23 December 2009.

Scope of the modification

The agreed changes refer to the prioritisation of the endpoints of the paediatric trial 1100.1518, specifically the shifting of AUCt,ss, Cmin,ss, Cmax,ss from the primary to the secondary endpoints.
Furthermore, a typographical error was corrected within the subset definition of group 2 in study 1100.1518.
A change in the timelines for study 1100.1518 was also operated, without affecting the end of the study agreed date.

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Opinion

The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree to the changes proposed by the applicant regarding the measures and the timelines of the paediatric investigation plan

The Icelandic and the Norwegian Paediatric Committee members do agree with the above-mentioned recommendation of the Paediatric Committee.

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

London, 15 January 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

THE MEASURES AND TIMELINES OF THE AGREED PAEDIATRIC INVESTIGATION PLAN AND THE SUBSET(S) OF THE PAEDIATRIC POPULATION AND CONDITION(S) COVERED BY THE WAIVER

A. CONDITION(S)

Human immunodeficiency virus 1 infection

B. WAIVER

Human immunodeficiency virus 1 infection

- **Condition**

The waiver applies to:

– Preterm newborn infants, term newborn infants (from birth to less than 28 days), Infants and toddlers (from 28 days to less than 24 months), Children (from 2 to less than 3 years), for the 400 mg, 100 mg and 50 mg prolonged release tablet for oral use on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Human immunodeficiency virus 1 infection

- **Proposed PIP indication**

- **Subset(s) of the paediatric population concerned by the paediatric development**

From 3 to less than 18 years.

- **Formulation(s)**

400 mg, 100 mg and 50 mg prolonged release tablet for oral use

- **Studies**

Area	Number of studies	Description
Quality	2	Development of a 50 mg strength of the prolonged release tablet Development of a 100 mg strength of the prolonged release tablet
Non-clinical		Not applicable.
Clinical	2	Open-label, multiple dose, cross-over study to evaluate the steady-state pharmacokinetic parameters of nevirapine extended release tablets in HIV-1 infected children, with an optional extension phase (optional extension phase not required for completion of the paediatric investigation plan) Single dose, parallel group design study comparing the pharmacokinetic parameters of 200 mg Nevirapine extended release tablets given as 2 x 100 mg tablets and as 4 x 50 mg tablets in male adult healthy volunteers.

Measures to address long term follow-up in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	**By July 2010**
Deferral for some or all studies contained in the paediatric investigation plan:	**No**

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	Invented name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Content	Package size
EU/1/97/055/001	Viramune	200 mg	Tablet	Oral use	blister (PVC/alu)		60 tablets
EU/1/97/055/002	Viramune	50 mg/5 ml	Oral suspension	Oral use	bottle (HDPE)	240 ml (10 mg/ml)	1 bottle + 5 ml measuring syringe
EU/1/97/055/003	Viramune	200 mg	Tablet	Oral use	blister (PVC/alu)		120 tablets
EU/1/97/055/004	Viramune	200 mg	Tablet	Oral use	blister (PVC/alu)		14 tablets