European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 11 August 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a waiver for midazolam hydrochloride (EMEA-000395-PIP01-08 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 application submitted by Auralis Limited on 8 October 2008 under Article 15 of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 26 June 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation**,**

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 agreement of a Paediatric Investigation Plan and on the granting of a waiver,

(2) It is therefore appropriate to adopt a Decision agreeing a Paediatric Investigation Plan,

(3) 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 Paediatric Investigation Plan for midazolam hydrochloride, oromucosal solution, oromucosal 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 agreed.

Article 3

A waiver for midazolam hydrochloride, oromucosal solution, oromucosal 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 3

This decision is addressed to Auralis Limited, Daresbury Innovation Centre, Daresbury International Science and Technology Park, Keckwick Lane, Daresbury, Runcorn, WA4 4FS, United Kingdom.

Done at London, 11 August 2009

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. EMEA/PDCO/358266/2009
EMEA-000395-PIP01-08

OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN AND A WAIVER

Scope of the application

Active substance(s):
Midazolam hydrochloride

Condition(s):
Epileptic seizures

Pharmaceutical form(s):
Oromucosal solution

Route(s) of administration:
Oromucosal use

Name/corporate name of the PIP applicant:
Auralis Limited

Basis for opinion

Pursuant to Article 15 of Regulation (EC) No 1901/2006 as amended, Auralis Limited submitted for agreement to the EMEA on 8 October 2008 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 13 November 2008.

Supplementary information was provided by the applicant on 30 March 2009.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,

- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded 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 measures and timelines of the agreed paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annex(es) and appendix.

London, 26 June 2009

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)

Epileptic seizures

B. WAIVER

- **Condition**

Epileptic seizures

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 3 months).
- for oromucosal solution, oromucosal 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**

Epileptic seizures

- **Proposed PIP indication**

Treatment of acute seizures in children (from 3 months to less than 18 years) known to have epileptic seizures.

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

From 3 months to less than 18 years.

- **Formulation(s)**

Oromucosal solution, oromucosal use, 5 mg/ml

- **Studies**

Area	Number of studies	Description
Quality	1	Development age-specified pre-filled syringes
Non-clinical	-	Not applicable.
Clinical	1	Open label, single dose, pharmacokinetic study of oromucosal midazolam administered to children from 3 months to less than 18 years undergoing routine elective surgery.

Measures to address long term follow-up of potential safety issues and/or efficacy in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	**By March 2011**
Deferral for some or all studies contained in the paediatric investigation plan:	**No**