



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/114384/2013

European Medicines Agency decision

P/0074/2013

of 26 March 2013

on the agreement of a paediatric investigation plan for clonidine (Hydrochloride) (EMA-001316-PIP01-12) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This Decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.



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on the agreement of a paediatric investigation plan for clonidine (Hydrochloride) (EMA-001316-PIP01-12) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Therakind Limited on 2 July 2012 under Article 16(1) of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 8 February 2013, in accordance with Article 18 of Regulation (EC) No 1901/2006,

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

Whereas:

- (1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a paediatric investigation plan.
- (2) It is therefore appropriate to adopt a decision agreeing a 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

A paediatric investigation plan for clonidine (Hydrochloride), solution for infusion, intravenous 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 2

This decision is addressed to Therakind Limited, Winston House, 2 Dollis Park, Finchley, N3 1HF London, United Kingdom.

Done at London, 26 March 2013

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/753621/2012 **Corr**

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan

EMA-001316-PIP01-12

Scope of the application

Active substance(s):

Clonidine (Hydrochloride)

Condition(s):

Sedation

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Intravenous use

Name / corporate name of the PIP applicant:

Therakind Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Therakind Limited submitted for agreement to the European Medicines Agency on 2 July 2012 an application for a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 9 August 2012.

Supplementary information was provided by the applicant on 19 November 2012.

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.

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 are set out in the Annex I.

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

London, 8 February 2013

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed Paediatric Investigation Plan

1. Waiver

Not applicable.

2. Paediatric Investigation Plan

2.1. Condition: Sedation

2.1.1. Indication(s) targeted by the PIP

Sedation in intensive care.

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for infusion.

2.1.4. Measures

Area	Number of measures	Description
Quality	1	Measure 1: Development of three different strengths (ready-to-use) vials for intravenous infusion - appropriate for the complete paediatric population.
Non-clinical	0	Not applicable.
Clinical	1	Measure 2: Double blind randomised, multicentre, active controlled trial to evaluate pharmacokinetics, safety and efficacy of Clonidine (Hydrochloride) for sedation in children from birth to less than 18 years of age.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2017
Deferral for one or more measures contained in the paediatric investigation plan:	No