EMA/671995/2022

European Medicines Agency decision

P/0334/2022

of 10 August 2022

on the refusal of a modification of an agreed paediatric investigation plan for chloroprocaine (hydrochloride) (Ampres), (EMEA-000639-PIP03-16-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

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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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0014/2018 issued on 30 January 2018 and decision P/0382/2019 issued on 4 December 2019,

Having regard to the application submitted by Sintetica GmbH on 18 March 2022 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 24 June 2022, in accordance with Article 22 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 refusal of changes to the agreed paediatric investigation plan and to the deferral.

(2) It is therefore appropriate to adopt a decision on the refusal of changes to the agreed paediatric investigation plan, including changes to the deferral.

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for chloroprocaine (hydrochloride) (Ampres), solution for injection, perineural use, including changes to the deferral, 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 refused.

Article 2

This decision is addressed to Sintetica GmbH, Albersloher Weg 11, D-48155 – Münster, Germany.

EMA/PDCO/183945/2022
Amsterdam, 24 June 2022

Opinion of the Paediatric Committee on the refusal of a modification of an agreed Paediatric Investigation Plan

EMEA-000639-PIP03-16-M02

Scope of the application

Active substance(s):

Chloroprocaine (hydrochloride)

Invented name:

Ampres

Condition(s):

Peripheral nerve block (local anaesthesia by perineural injection)

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Perineural use

Name/corporate name of the PIP applicant:

Sintetica 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, Sintetica GmbH submitted to the European Medicines Agency on 18 March 2022 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0014/2018 issued on 30 January 2018 and decision P/0382/2019 issued on 4 December 2019.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 25 April 2022.

Opinion

1. 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 refuse the changes proposed by the applicant regarding the paediatric investigation plan and the deferral.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan remain unchanged and are set out in the Annex I.

3. The scientific conclusions and the grounds for refusal are set out in the summary report appended to this opinion.

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

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 (PIP)

1. Waiver

Not applicable

2. Paediatric investigation plan

2.1. Condition:

Peripheral nerve block (local anaesthesia by perineural injection)

2.1.1. Indication(s) targeted by the PIP

Peripheral nerve block (local anaesthesia by perineural injection)

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 injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	1	Study 1: Evaluation of spinal toxicity following intrathecal 2-chloroprocaine injection in juvenile rats
Clinical studies	1	Study 2: Prospective, randomised, multicentre, double blind, parallel active groups, concentration-response model trial to assess the efficacy of chloroprocaine 1% and 2% in the paediatric population for a successful peripheral nerve block (CHL.2/04-2015)
Extrapolation, modelling and simulation studies	1	Study 3: Extrapolation of chloroprocaine efficacy in the paediatric population
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By July 2020
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Local anaesthesia

Authorised indication(s):

- Local anaesthesia (intrathecal anaesthesia) for adult patients

Authorised pharmaceutical form(s):

Solution for injection

Authorised route(s) of administration:

Intrathecal use