EMADOC-1700519818-2068697

European Medicines Agency decision

EMA/PE/0000241152

of 24 April 2025

on the acceptance of a modification of an agreed paediatric investigation plan for chloroprocaine hydrochloride (Ampres, associated names: Clorotekal, Decelex) 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.

European Medicines Agency decision

EMA/PE/0000241152

of 24 April 2025

on the acceptance of a modification of an agreed paediatric investigation plan for chloroprocaine hydrochloride (Ampres, associated names: Clorotekal, Decelex) 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 726/2004[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, the decision P/0382/2019 issued on 4 December 2019, the decision P/0334/2022 issued on 10 August 2022 and the decision P/0084/2024 issued on 15 March 2024,

Having regard to the application submitted by Sintetica GmbH on 19 December 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 28 March 2025, 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 acceptance of changes to the agreed paediatric investigation plan and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance 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, associated names: Clorotekal, Decelex), including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Sintetica GmbH, Albersloher Weg 11, Hafen, 48155 - Muenster, Germany.

EMADOC-1700519818-1863828

Amsterdam, 28 March 2025

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

EMA/PE/0000241152

Scope of the application

Active substance(s):

Chloroprocaine (hydrochloride)

Invented name and authorisation status:

See Annex II

Condition(s):

Peripheral nerve block (local anesthesia by perineural injection)

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Perineural use

Name/corporate name of the PIP applicant:

Sintetica GmbH

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sintetica GmbH submitted to the European Medicines Agency on 19 December 2024 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0014/2018 issued on 30 January 2018, the decision P/0382/2019 issued on 4 December 2019, the decision P/0334/2022 issued on 10 August 2022 and the decision P/0084/2024 issued on 15 March 2024.

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

The procedure started on 27 Janaury 2025.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

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 agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

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

2. The measures and timelines of the 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 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

1.1. Condition:

Peripheral nerve block (local anaesthesia by perineural injection)

The waiver applies to:

- preterm and term newborn infants from birth to less than 28 days of age;
- solution for injection, perineural use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

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 28 days to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable
Non-clinical studies	**Study 1** Evaluation of spinal toxicity following intrathecal 2-chloroprocaine injection in juvenile rats
Clinical studies	**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	**Study 3** Extrapolation of chloroprocaine efficacy in the paediatric population
Other studies	Not applicable
Other measures	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 December 2025
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Intrathecal anaesthesia

Authorised indication(s):

- Spinal anaesthesia in adults where the planned surgical procedure should not exceed 40 minutes
  - Invented name(s): Ampres, Associated names: Clorotekal, Decelex
  - Authorised pharmaceutical form(s): Solution for injection
  - Authorised route(s) of administration: Intrathecal use
  - Authorised via decentralised procedure

2. Peripheral nerve block (local anesthesia by perineural injection)

Authorised indication(s):

- Perineural anaesthesia (peripheral nerve block) in adults for short-duration surgeries (not exceeding 60 minutes)
  - Invented name(s): Ampres, Associated names: Clorotekal, Decelex
  - Authorised pharmaceutical form(s): Solution for injection
  - Authorised route(s) of administration: Perineural use
  - Authorised via decentralised procedure