EMADOC-1700519818-1855179

European Medicines Agency decision

EMA/PE/0000228333

of 24 January 2025

on the acceptance of a modification of an agreed paediatric investigation plan for sufentanil (citrate) / ketamine (hydrochloride), 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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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/0413/2019 issued on 6 December 2019, the decision P/0177/2022 issued on 13 May 2022, the decision P/0320/2023 issued on 11 August 2023 and the decision P/0282/2024 issued on 16 August 2024,

Having regard to the application submitted by Cessatech A/S on 5 September 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 13 December 2024, 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.

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

[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 sufentanil (citrate) / ketamine (hydrochloride), 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 Cessatech A/S, Strandvejen 60, 2900 Hellerup, Denmark.

EMADOC-1700519818-1690405
Amsterdam, 13 December 2024

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

EMA/PE/0000228333

Scope of the application

Active substance(s):

Sufentanil (citrate) / ketamine (hydrochloride)

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of acute pain

Pharmaceutical form(s):

Nasal spray, solution

Route(s) of administration:

Intranasal use

Name/corporate name of the PIP applicant:

Cessatech A/S

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Cessatech A/S submitted to the European Medicines Agency on 5 September 2024 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0413/2019 issued on 6 December 2019, the decision P/0177/2022 issued on 13 May 2022, the decision P/0320/2023 issued on 11 August 2023 and the decision P/0282/2024 issued on 16 August 2024.

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

The procedure started on 14 October 2024.

Scope of the modification

Some measures 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 in the scope set out in the Annex I of this opinion.

   The Paediatric Committee members of Liechtenstein and Norway agree 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:

Treatment of acute pain

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- nasal spray, solution; intranasal use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition:

Treatment of acute pain

2.1.1. Indication(s) targeted by the PIP

Treatment of acute pain in children and adolescents from 1 year to less than 18 years of age in a hospital or prehospital setting

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

From 1 year to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Nasal spray, solution

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1** An exploratory, nonrandomised open-label trial to investigate a paediatric formulation of intranasal sufentanil and ketamine for procedural pain and to characterize its pharmacokinetic profile (PDC 01-0201) **Study 2** A registry study of the free combination of intranasal sufentanil and s-ketamine for treatment of procedural pain in children 1 to less than 18 years of age at a tertiary hospital in Sweden, including

	retrospective data from 10 years of routine clinical care (PDC 01-0203) **Study 3** Randomised cross-over study to investigate the absolute bioavailability of intranasal sufentanil/ketamine in a standardized study set-up with healthy adult volunteers (PDC 01-0204) **Study 4** Randomised, double-blind parallel-group controlled trial to investigate the concentration-effect relationship, efficacy and dose-response of intranasal (IN) sufentanil/ketamine versus IN sufentanil, IN ketamine and IN placebo in adults, using a standardised dental impaction model (PDC 01-0205) **Study 5** A pharmacokinetic study of intranasal sufentanil/ketamine fixed combination in children 1 to less than 18 years of age undergoing elective surgery to provide PK data in children aged 1-2 years and collection of supplemental PK data in children 2-18 years (PDC 01-0206) **Study 6** Open-label, prospective study to assess safety, tolerability, analgesic effect and feasibility of intranasal sufentanil/ketamine in paediatric patients with moderate to severe pain, in an acute care setting (PDC 01-0202)
Extrapolation, modelling and simulation studies	**Study 7** A modelling and simulation study building a population PK model combining adult and paediatric data (including simulations of PK after administration of multiple (two) doses of intranasal sufentanil/ketamine fixed combination in children (PDC 01-0207) **Study 8** Extrapolation of efficacy between adults and children based on similar exposure (PDC 01-0208)
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 April 2025
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.