EMA/528355/2023

# European Medicines Agency decision

P/0503/2023

of 29 December 2023

on the acceptance of a modification of an agreed paediatric investigation plan for iron as ferric maltol (Feraccru), (EMEA-001195-PIP01-11-M07) 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/0228/2013 issued on 23 September 2013, the decision P/0069/2016 issued on 18 March 2016, the decision P/0102/2017 issued on 11 April 2017, the decision P/0164/2017 issued on 3 July 2017, the decision P/0330/2019 issued on 11 September 2019, and the decision P/0316/2021 issued on 11 August 2021,

Having regard to the application submitted by Norgine BV on 1 August 2023 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 10 November 2023, 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 iron as ferric maltol (Feraccru), capsule, hard, oral suspension, oral use, 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 Norgine BV, Antonio Vivaldistraat 150, 1083 HP – Amsterdam, The Netherlands.

EMA/PDCO/363593/2023
Amsterdam, 10 November 2023

# Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan and to the deferral

EMEA-001195-PIP01-11-M07

## Scope of the application

**Active substance(s):**

Iron as ferric maltol

**Invented name and authorisation status:**

See Annex II

**Condition(s):**

Treatment of iron deficiency

**Pharmaceutical form(s):**

Capsule, hard

Oral suspension

**Route(s) of administration:**

Oral use

**Name/corporate name of the PIP applicant:**

Norgine BV

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Norgine BV submitted to the European Medicines Agency on 1 August 2023 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/0228/2013 issued on 23 September 2013, the decision P/0069/2016 issued on 18 March 2016, the decision P/0102/2017 issued on 11 April 2017, the decision P/0164/2017 issued on 3 July 2017, the decision P/0330/2019 issued on 11 September 2019, and the decision P/0316/2021 issued on 11 August 2021.

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

The procedure started on 11 September 2023.

## 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.
2. The measures and timelines of the 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 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 iron deficiency

The waiver applies to:

- all paediatric patients from birth to less than 2 years of age;
- capsule, hard, oral suspension, oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

# 2. Paediatric Investigation Plan

## *2.1. Condition*

Treatment of iron deficiency

### 2.1.1. Indication(s) targeted by the PIP

Treatment of iron deficiency anaemia (IDA)

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

From 2 years to less than 18 years of age

### 2.1.3. Pharmaceutical form(s)

Capsule, hard

Oral suspension

### 2.1.4. Measures

| Area | Description |
|---|---|
| Quality-related studies | **Study 1**<br><br>Development of an age-appropriate oral suspension formulation, supplied with a dosing device. |
| Non-clinical studies | Not applicable. |
| Clinical studies | **Study 2 (ST10-01-103)**<br><br>Open-label, randomised, multiple-dose, parallel assignment trial to evaluate pharmacokinetics and tolerability in children and adolescents with iron deficiency from 10 to less than 18 years of age.<br><br>**Study 3 (ST10-01-305)**<br><br>Randomised, open-label, active-controlled, randomised, multicentre, comparative trial to evaluate safety and efficacy of Iron as iron maltol |

| | |
|---|---|
| | (iron(III)-maltol complex) (ST10) compared to oral ferrous sulphate in children from 2 to less than 18 years of age with iron-deficiency anaemia. |
| Extrapolation, modelling and simulation studies | Not applicable |
| 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 October 2024 |
| 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. Treatment of iron deficiency

Authorised indication(s):

Treatment of iron deficiency (ID) in adult patients

- Invented name(s): Feraccru 30 mg
- Authorised pharmaceutical form(s): Capsule, hard
- Authorised route(s) of administration: Oral use
- Authorised via centralised procedure