MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-100036-PIP01-21-M01

Scope of the Application

Active Substance(s)

Ferric Maltol; FERRIC MALTOL

Condition(s)

Treatment of Iron deficiency anaemia (IDA)

Pharmaceutical Form(s)

Oral suspension, Capsule, hard

Route(s) of Administration

Oral use

Name / Corporate name of the PIP applicant

Norgine Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Norgine Limited submitted to the licensing authority on 09/03/2021 16:12 GMT an application for a Modification

The procedure started on 17/08/2021 15:59 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to the deferral

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

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-100036-PIP01-21-M01

Of 05/10/2021 11:29 BST

On the adopted decision for Ferric Maltol; FERRIC MALTOL (MHRA-100036-PIP01-21-M01) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for Ferric Maltol; FERRIC MALTOL, Oral suspension, Capsule, hard , Oral use .

This decision is addressed to Norgine Limited, Norgine House, Widewater Place, Moorhall Road, Harefield, United Kingdom, UB9 6NS

ANNEX I

1. Waiver

1.1 Condition:

Treatment of Iron deficiency The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Oral suspension; Capsule, hard Route(s) of administration: Oral use Reason for granting waiver: on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of Iron deficiency

2.2 Indication(s) targeted by the PIP:

Treatment of iron deficiency anaemia (IDA)

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 2 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Oral suspension; Capsule, hard

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate oral suspension formulation, supplied with dosing device
Non-Clinical Studies	0	Not applicable
Clinical Studies	2	Study 2 (ST10-01-103) 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 Study 3 (ST10-01-305) Randomised, open-label, active controlled multicentre trial to evaluate safety and efficacy of Iron as ferric maltol (iron (III)-maltol complex) (ST10) compared to oral ferrous sulphate in children from 2 years to less than 18 years of age with iron deficiency anaemia.
Extrapolation, Modeling & Simulation Studies	0	Not applicable
Other Studies	0	Not applicable
Other Measures	0	Not applicable

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	30/06/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes