

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

MHRA-100284-PIP01-21-M01

Scope of the Application

Active Substance(s)

MEXILETINE HYDROCHLORIDE

Condition(s)

Treatment of myotonic disorders

Pharmaceutical Form(s)

Capsule, hard; Oral solution

Route(s) of Administration

Oral use

Name / Corporate name of the PIP applicant

Lupin Healthcare UK Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Lupin Healthcare UK Ltd submitted to the licensing authority on 14/10/2021 12:05 BST an application for a Modification

The procedure started on 29/07/2022 15:22 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-100284-PIP01-21-M01

Of 26/08/2022 15:17 BST

On the adopted decision for MEXILETINE HYDROCHLORIDE (MHRA-100284-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 MEXILETINE HYDROCHLORIDE, Capsule, hard; Oral solution , Oral use; Gastric use .

This decision is addressed to Lupin Healthcare UK Ltd, The Urban Building, Second Floor, Slough, United Kingdom, SL1 2BE

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of myotonic disorders

2.2 Indication(s) targeted by the PIP:

Symptomatic treatment of myotonic disorders

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

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

2.4 Pharmaceutical Form(s):

Oral solution; Capsule, hard

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of age appropriate solid formulation (capsule, not containing erythrosine as colorant) in lower strengths appropriate to the paediatric population Study 2 Deleted during procedure MHRA-100284-PIP01-21-M01.
Non-Clinical Studies	1	Study 3 11-week toxicity study in juvenile rats with a 4-week recovery period.
Clinical Studies	3	Study 4 Open-label, non-comparative study to evaluate the PK, safety and efficacy of mexiletine in children and adolescents 6 years to less than 18 years of age with clinical symptoms or signs of myotonic disorders. (MEX-NM-301, EudraCT number 2019-003757-28) Study 5 Prospective, long-term observational study (registry) of paediatric myotonic disorder patients from birth to less than 6 years of age who are treated with mexiletine. (MEX-NM-401) Study 6 Deleted during procedure EMEA-00212-PIP01-16-M01. Study 7 Open-label follow-up study evaluating the long-term safety and efficacy of mexiletine in children with myotonic disorders who have completed the initial paediatric studies. (MEX-NM-303, EudraCT number 2019-003758-97)
Extrapolation, Modeling & Simulation Studies	1	Study 8 PK modelling study to support dosing recommendations in children
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:	Yes
Date of completion of the paediatric investigation plan:	31/01/2025
Deferral of one or more studies contained in the paediatric investigation plan:	Yes