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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

grant a product specific waiver

MHRA-101287-PIP01-23

Scope of the Application

Active Substance(s)

SUMATRIPTAN; NAPROXEN SODIUM

Condition(s)

Treatment of migraine headaches

Pharmaceutical Form(s)

Film-coated tablets

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Orion Corporation

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Orion Corporation submitted to the licensing authority on 30/11/2023 18:23 GMT an application for a Waiver

The procedure started on 05/12/2023 06:52 GMT

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 grant a product specific waiver

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-101287-PIP01-23

Of 06/12/2023 12:21 GMT

On the adopted decision for SUMATRIPTAN; NAPROXEN SODIUM (MHRA-101287-PIP01-23) in accordance with the Human Medicines Regulations 2012.

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

Granting a waiver in all age groups for the listed condition(s)

This decision applies to a Waiver for SUMATRIPTAN; NAPROXEN SODIUM, Film-coated tablets , ORAL USE .

This decision is addressed to Orion Corporation, Orionintie 1, Espoo, FINLAND, FI-02200

ANNEX I

1. Waiver

1.1 Condition:

Treatment of migraine headaches The waiver applies / applied to: Paediatric Subset(s): All subsets of the paediatric population from birth to less than 18 years of age Pharmaceutical form(s): Film-coated tablets Route(s) of administration: ORAL USE Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Not Applicable

2.2 Indication(s) targeted by the PIP:

Not Applicable

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

Not Applicable

2.4 Pharmaceutical Form(s):

Not Applicable

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures		
Non-Clinical Studies		
Clinical Studies		
Extrapolation, Modeling & Simulation Studies		
Other Studies		
Other Measures		

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

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	