



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/87776/2014

## European Medicines Agency decision

P/0043/2014

of 26 February 2014

on the acceptance of a modification of an agreed paediatric investigation plan for rupadatine fumarate (Rupafin and associated names) (EMEA-000582-PIP01-09-M03) 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<sup>1</sup>,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency<sup>2</sup>,

Having regard to the European Medicines Agency's decision P/29/2010 issued on 8 March 2010, the decision P/301/2011 issued on 20 December 2011, and the decision P/0193/2013 issued on 13 August 2013,

Having regard to the application submitted by J. Uriach y Compañía, S.A. on 22 November 2013 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 14 February 2014, 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.

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<sup>1</sup> OJ L 378, 27.12.2006, p.1.

<sup>2</sup> OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

**Article 1**

Changes to the agreed paediatric investigation plan for rupadatine fumarate (Rupafin and associated names), tablets, granules, oral liquid, oral use, 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 J. Uriach y Compañía, S.A., Poligon Industrial Riera de Caldes Avinguda Camí Reial, 51-57, 08184 Palau-Solita i Plegamans, 08184 – Barcelona, Spain

Done at London, 26 February 2014

For the European Medicines Agency  
Guido Rasi  
Executive Director  
(Signature on file)



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/PDCO/738967/2013

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

EMA-000582-PIP01-09-M03

### Scope of the application

**Active substance(s):**

Rupadatine fumarate

**Invented name:**

Rupafin and associated names

**Condition(s):**

Treatment of allergic rhinitis

Treatment of chronic idiopathic urticaria

**Authorised indication(s):**

See Annex II

**Pharmaceutical form(s):**

Tablets

Granules

Oral liquid

**Route(s) of administration:**

Oral use

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

J. Uriach y Compañía, S.A.

**Information about the authorised medicinal product:**

See Annex II



## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, J. Uriach y Compañía, S.A. submitted to the European Medicines Agency on 22 November 2013 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/29/2010 issued on 8 March 2010, the decision P/301/2011 issued on 20 December 2011, and the decision P/0193/2013 issued on 13 August 2013.

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

The procedure started on 18 December 2013.

## Scope of the modification

Modification of some measures and timelines

## 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 Norwegian Paediatric Committee member agrees 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.

London, 14 February 2014

On behalf of the Paediatric Committee  
Dr Dirk Mentzer, Chairman  
(Signature on file)

## **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**

# 1. Waiver

## 1.1. *Condition: treatment of allergic rhinitis*

The waiver applies to:

- Children from birth to less than 2 years;
- for tablets, granules and oral liquid for oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s);
- Adolescents from 12 to less than 18 years;
- for tablets and oral liquid for oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.

## 1.2. *Condition: treatment of chronic idiopathic urticaria*

- Children from birth to less than 2 years;
- for tablets, granules and oral liquid for oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s);
- Adolescents from 12 to less than 18 years;
- for tablets and oral liquid for oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.

# 2. Paediatric Investigation Plan

## 2.1. *Condition: treatment of allergic rhinitis*

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

Symptomatic treatment of allergic rhinitis.

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

From 2 to less than 12 years of age.

### 2.1.3. Pharmaceutical form(s)

Tablets

Granules

Oral liquid

#### 2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	1	<b>Study 1</b> Development of oral liquid for children from 2 to less than 12 years of age
Non-clinical studies	0	Not applicable.
Clinical studies	3	<b>Study 2</b> Open-label study to evaluate pharmacokinetics (after a single dose) and pharmacodynamics (after 28 days dosing) with safety and efficacy assessment over 28 days of treatment. <b>Study 3</b> Open-label study to evaluate pharmacokinetics (single dose), efficacy, tolerability and safety (single and multiple doses) in children from 2 to less than 5 years with allergic rhinitis. <b>Study 4</b> Randomised, double-blind, placebo-controlled, multi-centre, repeated dose safety and efficacy study in children from 6 to less than 12 years with allergic rhinitis.
Extrapolation, modelling & simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

#### 2.2. Condition: treatment of chronic idiopathic urticaria

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

Symptomatic treatment of chronic idiopathic urticaria

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

From 2 to less than 12 years of age.



### 2.2.3. Pharmaceutical form(s)

Tablets

Granules

Oral liquid

### 2.2.4. Measures

Area	Number of studies	Description
Quality- related studies	1	<b>Study 1</b> Development of oral liquid for children from 2 to less than 12 years of age
Non-clinical studies	0	Not applicable.
Clinical studies	1	<b>Study 5</b> Randomised, double-blind, three-arm, parallel-group, multicentre, repeated dose study to evaluate efficacy and safety in children from 2 to less of 12 years with chronic idiopathic urticaria.
Extrapolation, modelling & simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

## 3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By June 2013
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

## **Annex II**

### **Information about the authorised medicinal product**

**Condition(s) and authorised indication(s):**

1. Treatment of allergic rhinitis

Authorised indication(s):

- Symptomatic treatment of allergic rhinitis

2. Treatment of chronic idiopathic urticaria

Authorised indication(s):

- Symptomatic treatment of chronic idiopathic urticaria

**Authorised pharmaceutical form(s):**

Tablet, oral liquid

**Authorised route(s) of administration:**

Oral use