European Medicines Agency

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P/29/2010

EUROPEAN MEDICINES AGENCY DECISION

of 8 March 2010

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver for rupatadine fumarate (Rupafin and associated names) (EMEA-000582-PIP01-09) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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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 as amended 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the application submitted by J. Uriach y Compañía, S.A. on 24 April 2009 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation and a deferral under Article 20 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 January 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation and Article 21 of said Regulation**,**

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver,

(2) It is therefore appropriate to adopt a Decision agreeing a Paediatric Investigation Plan,

(3) It is therefore appropriate to adopt a Decision granting a deferral,

(4) It is therefore appropriate to adopt a Decision granting a waiver.

[1] OJ L 378, 27.12.2006, p.1
[2] OJ L 136, 30.4.2004, p. 1

HAS ADOPTED THIS DECISION:

Article 1

A Paediatric Investigation Plan for rupatadine fumarate (Rupafin and associated names), tablets and oral liquid, oral use, the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for rupatadine fumarate (Rupafin and associated names), tablets and oral liquid, oral use, the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver for rupatadine fumarate (Rupafin and associated names), tablets and oral liquid, oral use, the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to J. Uriach y Compañía, S.A., Póligon Industrial Riera de Caldes Avinguda Camí Reial, 51-57, 08184 Palau-Sòlita i Plegamans, Barcelona, Spain.

Done at London, 8 March 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMA/PDCO/14364/2010
EMEA-000582-PIP01-09

OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL AND A WAIVER

Scope of the application

Active substance(s):
Rupatadine fumarate

Invented name:
Rupafin and associated names

Condition(s):
Allergic rhinitis
Chronic idiopathic urticaria

Pharmaceutical form(s):
Tablets
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 16(1) of Regulation (EC) No 1901/2006 as amended, J. Uriach y Compañía, S.A submitted for agreement to the EMA on 24 April 2009 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 23 July 2009.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 18 of said Regulation;

- to grant a deferral in accordance with Article 21 of said Regulation;

- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Articles 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population;

- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The Icelandic and the Norwegian Paediatric Committee members do agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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 Agency, together with its annexes.

London, 15 January 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

THE MEASURES AND TIMELINES OF THE AGREED PAEDIATRIC INVESTIGATION PLAN AND THE SUBSET(S) OF THE PAEDIATRIC POPULATION AND CONDITION(S) COVERED BY THE WAIVER

A. CONDITION(S)

Allergic rhinitis
Chronic idiopathic urticaria

B. WAIVER

- **Condition**

Allergic rhinitis

The waiver applies to:

- Children from birth to less than 2 years for tablets 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.

- **Condition**

Chronic idiopathic urticaria

The waiver applies to:

- Children from birth to less than 2 years for tablets 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.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Allergic rhinitis

- **Proposed PIP indication**

Symptomatic treatment of allergic rhinitis

- **Subset(s) of the paediatric population concerned by the paediatric development**

From 2 to less than 12 years.

- **Formulation(s)**
    - Tablets 10 mg for oral use
    - Oral liquid 1mg/ml for oral use

- **Studies**

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	3	• 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. • Open-label study to evaluate pharmacokinetics (single dose), efficacy, tolerability and safety (single and multiple dose) in children from 2 to less than 5 years with allergic rhinitis • 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

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	**Yes**
Date of completion of the paediatric investigation plan:	**By June 2012**
Deferral for some or all studies contained in the paediatric investigation plan:	**Yes**

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

Invented name Name	**Strength**	**Pharmaceutical form**	**Route of administration**
Rupafin and associated names	10 mg	Tablets	Oral