

EMA/953992/2011

European Medicines Agency decision

P/301/2011

of 20 December 2011

on the acceptance of a modification of an agreed paediatric investigation plan for rupatadine fumarate (Rupafin and associated names), (EMA-000582-PIP01-09-M01) 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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/29/2010 issued on 8 March 2010,

Having regard to the application submitted by J. Uriach y Compañía, S.A. on 26 August 2011 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 11 November 2011, in accordance with Article 22 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 of said Regulation,

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 and to the deferral and to the waiver.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral and the 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

Changes to the agreed paediatric investigation plan for rupatadine fumarate (Rupafin and associated names), tablets, orodispersible tablets, oral liquid, oral use, including changes to the deferral, and the waiver, 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., Póligon Industrial Riera de Caldes Avinguda Camí Reial, 51-57, 08184 - Palau-Sòlita i Plegamans, Barcelona, Spain.

Done at London, 20 December 2011

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

EMA/PDCO/735206/2011

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

EMA-000582-PIP01-09-M01

Scope of the application

Active substance(s):

Rupatadine fumarate

Invented name:

Rupafin and associated names

Condition(s):

Allergic rhinitis

Chronic idiopathic urticaria

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Tablets

Orodispersible 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 22 of Regulation (EC) No 1901/2006 as amended, J. Uriach y Compañía, S.A. submitted to the European Medicines Agency on 26 August 2011 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 application for modification proposed changes to the agreed paediatric investigation plan, to the deferral and to the waiver.

The procedure started on 14 September 2011.

Scope of the modification

Some timelines of the Paediatric Investigation Plan have been modified and a waiver for a new pharmaceutical form has been added.

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, to the deferral and to the waiver in the scope set out in the Annex I of this opinion.

The Icelandic and the Norwegian Paediatric Committee member(s) agree(s) 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 annex(es) and appendix.

London, 11 November 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, 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: Allergic rhinitis

The waiver applies to:

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

1.2. Condition: Chronic idiopathic urticaria

The waiver applies to:

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

2. Paediatric Investigation Plan

2.1. Condition: 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 10 mg for oral use;
- Orodispersible tablets 10 mg for oral use;
- Oral liquid 1 mg/ml for oral use.

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	3	Study 1 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. Study 2 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. Study 3 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.

3. Follow-up, completion and deferral of PIP

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

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Allergic rhinitis

Authorised indications: Symptomatic treatment of allergic rhinitis

2. Chronic idiopathic urticaria

Authorised indications: Symptomatic treatment of chronic idiopathic urticaria

Invented name	Strength	Pharmaceutical form	Route of administration
Rupafin and associated names	10 mg	Tablet	Oral use