



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/247088/2013

European Medicines Agency decision

P/01115/2013

of 26 April 2013

on the agreement of a paediatric investigation plan and on the granting of a waiver for solifenacin (succinate) (Vesicare and associated names), (EMA-000573-PIP02-13) 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 application submitted by Astellas Pharma Europe B.V. on 22 February 2013 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 12 April 2013, in accordance with Article 18 of Regulation (EC) No 1901/2006, 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 agreement of a paediatric investigation plan 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 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 solifenacin (succinate) (Vesicare and associated names), oral suspension, film-coated tablet, 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 waiver for solifenacin (succinate) (Vesicare and associated names), oral suspension, film-coated tablet, 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

This agreed PIP covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/89/2010 issued on 1 June 2010, including subsequent modifications thereof.

Article 4

This decision is addressed to Astellas Pharma Europe B.V., Sylviusweg 62, 2300 AH – Leiden, The Netherlands.

Done at London, 26 April 2013

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/144715/2013

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a waiver

EMA-000573-PIP02-13

Scope of the application

Active substance(s):

Solifenacin (succinate)

Invented name:

Vesicare and associated names

Condition(s):

Treatment of neurogenic detrusor overactivity

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Oral suspension

Film-coated tablet

Route(s) of administration:

Oral use

Name / corporate name of the PIP applicant:

Astellas Pharma Europe B.V.

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, Astellas Pharma Europe B.V. submitted for agreement to the European Medicines Agency on 22 February 2013 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 20 March 2013.

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 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 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 European Medicines Agency, together with its annexes and appendix.

London, 12 April 2013

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: treatment of neurogenic detrusor overactivity

The waiver applies to:

- the paediatric population from birth to less than 6 months of age;
- for oral suspension, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

The waiver applies to:

- the paediatric population from birth to less than 18 years of age;
- for film-coated tablet, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition: treatment of neurogenic detrusor overactivity

2.1.1. Indication(s) targeted by the PIP

Treatment of detrusor overactivity in children with neurogenic bladder dysfunction.

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

From 6 months to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Oral suspension

2.1.4. Measures

Area	Number of studies	Description
Quality	1	Measure 1 Development of an oral liquid age-appropriate formulation.
Non-clinical	2	Measure 2 11-day dose range finding juvenile toxicity study in mice. Measure 3 12-week oral dose toxicity study in juvenile mice.

Area	Number of studies	Description
Clinical	3	Measure 4 Open-label, multicentre, single ascending dose study to evaluate pharmacokinetics, safety and tolerability of solifenacin succinate suspension in children from 5 to less than 18 years of age with overactive bladder. Measure 5 Open label, baseline-controlled, multicentre, sequential dose titration study to assess long-term efficacy, safety, and pharmacokinetics of solifenacin succinate suspension in children from 5 to less than 18 years of age with neurogenic detrusor overactivity. Measure 6 Open label, baseline-controlled, multicentre, sequential dose titration study to assess PK, efficacy and safety of solifenacin succinate suspension in children from 6 months to less than 5 years of age with neurogenic detrusor overactivity.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2014
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of overactive bladder

Authorised indication(s):

Symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome.

Authorised pharmaceutical formulation(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use