

EMA/680042/2012 **Corr**

European Medicines Agency decision

P/0273/2012

of 21 November 2012

on the acceptance of a modification of an agreed paediatric investigation plan for azilsartan medoxomil (Edarbi, Ipreziv), (EMA-000237-PIP01-08-M04) 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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on the acceptance of a modification of an agreed paediatric investigation plan for azilsartan medoxomil (Edarbi, Ipreziv), (EMA-000237-PIP01-08-M04) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/105/2009 issued on 15 June 2009, the decision P/234/2009 issued on 27 November 2009, the decision P/106/2010 issued on 25 June 2010 and the decision P/39/2011 issued on 4 February 2011,

Having regard to the application submitted by Takeda Global Research and Development Centre (Europe) Ltd on 13 July 2012 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 5 October 2012, 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.

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 azilsartan medoxomil (Edarbi, Ipreziv), tablets, granules for oral suspension, 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 Takeda Global Research and Development Centre (Europe) Ltd, 61 Aldwych, WC2B 4AE – London, United Kingdom.

Done at London, 21 November 2012

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/482419/2012 **Corr**

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

EMA-000237-PIP01-08-M04

Scope of the application

Active substance(s):

Azilsartan medoxomil

Invented name:

Edarbi

Ipreziv

Condition(s):

Treatment of hypertension

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Tablets

Granules for oral suspension

Route(s) of administration:

Oral use

Name / corporate name of the PIP applicant:

Takeda Global Research and Development Centre (Europe) Ltd

Information about the authorised medicinal product:

See Annex II



Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Takeda Global Research and Development Centre (Europe) Ltd submitted to the European Medicines Agency on 13 July 2012 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/105/2009 issued on 15 June 2009, the decision P/234/2009 issued on 27 November 2009, the decision P/106/2010 issued on 25 June 2010 and the decision P/39/2011 issued on 4 February 2011.

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

The procedure started on 9 August 2012.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

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, 5 October 2012

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 hypertension

The waiver applies to:

- preterm newborn infants, term newborn infants (from birth to less than 28 days), infants less than 1 year of age;
- for tablets and granules for oral suspension, oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan

2.1. Condition to be investigated

Treatment of hypertension

2.1.1. Indication targeted by the PIP

Treatment of essential and secondary hypertension.

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

From 1 year to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

- tablets
- granules for oral suspension.

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Development of age appropriate formulation (granules for oral suspension).
Non-clinical	2	1. Repeat-dose range-finding toxicity study in neonatal rats. 2. Repeat-dose toxicity study with recovery in neonatal rats.
Clinical	4	1. Relative bioavailability, safety, and tolerability study in adults. 2. Single-dose PK, safety, and tolerability of TAK 491 in children and adolescents.

		3. Randomized, double-blind, active-controlled, 6-week dose-ranging safety and efficacy study with a 2-week, randomised, double-blind, placebo-controlled withdrawal phase and 44-week open-label extension in children aged 6 years to less than 18 years with essential and secondary hypertension. 4. Randomized, double-blind, 6-week dose-ranging safety and efficacy study with a 2-week randomized double-blind, placebo-controlled withdrawal phase and 2-year open-label extension in young children 1 year and older and with a weight of less than 25 kg with mild to moderate secondary hypertension.
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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 April 2021
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. Treatment of hypertension

Authorised indication:

Treatment of essential hypertension in adults.

EMA Number	Invented name	Strength	Pharmaceutical form	Route of administration	Packaging	Package size
EU/1/11/735/001	Ipreziv	20 mg	Tablet	Oral use	blister (alu/alu)	14 tablets
EU/1/11/735/002	Ipreziv	20 mg	Tablet	Oral use	blister (alu/alu)	28 tablets
EU/1/11/735/003	Ipreziv	20 mg	Tablet	Oral use	blister (alu/alu)	56 tablets
EU/1/11/735/004	Ipreziv	20 mg	Tablet	Oral use	blister (alu/alu)	98 tablets
EU/1/11/735/005	Ipreziv	40 mg	Tablet	Oral use	blister (alu/alu)	14 tablets
EU/1/11/735/006	Ipreziv	40 mg	Tablet	Oral use	blister (alu/alu)	28 tablets
EU/1/11/735/007	Ipreziv	40 mg	Tablet	Oral use	blister (alu/alu)	56 tablets
EU/1/11/735/008	Ipreziv	40 mg	Tablet	Oral use	blister (alu/alu)	98 tablets
EU/1/11/735/009	Ipreziv	80 mg	Tablet	Oral use	blister (alu/alu)	28 tablets
EU/1/11/735/010	Ipreziv	80 mg	Tablet	Oral use	blister (alu/alu)	56 tablets
EU/1/11/735/011	Ipreziv	80 mg	Tablet	Oral use	blister (alu/alu)	98 tablets
EU/1/11/735/012	Ipreziv	20 mg	Tablet	Oral use	blister (alu/alu)	30 tablets
EU/1/11/735/013	Ipreziv	20 mg	Tablet	Oral use	blister (alu/alu)	90 tablets
EU/1/11/735/014	Ipreziv	40 mg	Tablet	Oral use	blister (alu/alu)	30 tablets
EU/1/11/735/015	Ipreziv	40 mg	Tablet	Oral use	blister (alu/alu)	90 tablets
EU/1/11/735/016	Ipreziv	80 mg	Tablet	Oral use	blister (alu/alu)	14 tablets
EU/1/11/735/017	Ipreziv	80 mg	Tablet	Oral use	blister (alu/alu)	30 tablets
EU/1/11/735/018	Ipreziv	80 mg	Tablet	Oral use	blister (alu/alu)	90 tablets
EU/1/11/734/001	Edarbi	20 mg	Tablet	Oral use	blister (alu/alu)	14 tablets

EMA Number	Invented name	Strength	Pharmaceutical form	Route of administration	Packaging	Package size
EU/1/11/734/002	Edarbi	20 mg	Tablet	Oral use	blister (alu/alu)	28 tablets
EU/1/11/734/003	Edarbi	20 mg	Tablet	Oral use	blister (alu/alu)	56 tablets
EU/1/11/734/004	Edarbi	20 mg	Tablet	Oral use	blister (alu/alu)	98 tablets
EU/1/11/734/005	Edarbi	40 mg	Tablet	Oral use	blister (alu/alu)	14 tablets
EU/1/11/734/006	Edarbi	40 mg	Tablet	Oral use	blister (alu/alu)	28 tablets
EU/1/11/734/007	Edarbi	40 mg	Tablet	Oral use	blister (alu/alu)	56 tablets
EU/1/11/734/008	Edarbi	40 mg	Tablet	Oral use	blister (alu/alu)	98 tablets
EU/1/11/734/009	Edarbi	80 mg	Tablet	Oral use	blister (alu/alu)	28 tablets
EU/1/11/734/010	Edarbi	80 mg	Tablet	Oral use	blister (alu/alu)	56 tablets
EU/1/11/734/011	Edarbi	80 mg	Tablet	Oral use	blister (alu/alu)	98 tablets
EU/1/11/734/012	Edarbi	20 mg	Tablet	Oral use	blister (alu/alu)	30 tablets
EU/1/11/734/013	Edarbi	20 mg	Tablet	Oral use	blister (alu/alu)	90 tablets
EU/1/11/734/014	Edarbi	40 mg	Tablet	Oral use	blister (alu/alu)	30 tablets
EU/1/11/734/015	Edarbi	40 mg	Tablet	Oral use	blister (alu/alu)	90 tablets
EU/1/11/734/016	Edarbi	80 mg	Tablet	Oral use	blister (alu/alu)	14 tablets
EU/1/11/734/017	Edarbi	80 mg	Tablet	Oral use	blister (alu/alu)	30 tablets
EU/1/11/734/018	Edarbi	80 mg	Tablet	Oral use	blister (alu/alu)	90 tablets