EMA/133035/2016

European Medicines Agency decision

P/0044/2016

of 26 February 2016

on the acceptance of a modification of an agreed paediatric investigation plan for tapentadol (hydrochloride) (Palexia and associated names, Yantil and associated names and Tapentadol and associated names) (EMEA-000486-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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Contact EMA www.ema.europa.eu/contact

European Medicines Agency decision

P/0044/2016

of 26 February 2016

on the acceptance of a modification of an agreed paediatric investigation plan for tapentadol (hydrochloride) (Palexia and associated names, Yantil and associated names and Tapentadol and associated names) (EMEA-000486-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 726/2004[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 European Medicines Agency's decision P/56/2009 issued on 24 March 2009, the decision P/0282/2013 issued on 8 November 2013, and the decision P/0097/2014 issued on 7 April 2014,

Having regard to the application submitted by Grünenthal GmbH on 6 November 2015 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 29 January 2016, 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 tapentadol (hydrochloride) (Palexia and associated names, Yantil and associated names and Tapentadol and associated names), prolonged-release tablet, prolonged-release granules, 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 superseded by the decision P/48/2009 granted on 24 March 2009 including all its subsequent modifications thereof.

Article 3

This decision is addressed to Grünenthal GmbH, Zieglerstrasse 6, 52078 – Aachen, Germany.

Done at London, 26 February 2016

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/66995/2016 corr
London, 29 January 2016

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

EMEA-000486-PIP01-08-M04

Scope of the application

Active substance(s):

Tapentadol (hydrochloride)

Invented name:

Palexia and associated names

Yantil and associated names

Tapentadol and associated names

Condition(s):

Treatment of chronic pain

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Prolonged-release tablet

Prolonged-release granules

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Grünenthal GmbH

Information about the authorised medicinal product:

See Annex II

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5510
Send a question via our website www.ema.europa.eu/contact

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Grünenthal GmbH submitted to the European Medicines Agency on 6 November 2015 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/56/2009 issued on 24 March 2009, the decision P/0282/2013 issued on 8 November 2013, and the decision P/0097/2014 issued on 7 April 2014.

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

The procedure started on 30 November 2015.

Scope of the modification

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

Closure of this Paediatric Investigation Plan which is superseded by the decision P/48/2009 granted on 24 March 2009 including all its subsequent modifications thereof.

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 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.

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 (PIP)

This Paediatric Investigation Plan has been closed and is superseded by P/48/2009 granted on 24 March 2009 including all its subsequent modifications. Refer to that decision for details on relevant measures.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of acute pain

Authorised indication(s):

- Relief of moderate to severe acute pain in adults, which can be adequately managed only with opioid analgesics.

2. Treatment of chronic pain

Authorised indication(s):

- Management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics.

Authorised pharmaceutical form(s):

Film-coated tablet

Prolonged-release tablet

Oral solution

Authorised route(s) of administration:

Oral use