



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/945464/2011

European Medicines Agency decision P/302/2011

of 20 December 2011

on the granting of a product specific waiver for esketamine (hydrochloride) (EMEA-000770-PIP02-11)
in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Only the English text is authentic.



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on the granting of a product specific waiver for esketamine (hydrochloride) (EMEA-000770-PIP02-11)
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 application submitted by Auris Medical Limited on 8 August 2011 under Article 13 of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 11 November 2011 in accordance with Article 13 of Regulation (EC) No 1901/2006,

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

Whereas:

- (1) The Paediatric Committee has given an opinion on the granting of a product specific waiver.
- (2) 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 waiver for esketamine (hydrochloride), gel for injection, intratympanic 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 2

This decision is addressed to Auris Medical Limited, The Black Church, St. Mary's Place, 7 – Dublin, Ireland.

Done at London, 20 December 2011

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



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EMA/PDCO/696734/2011

Opinion of the Paediatric Committee on the granting of a product-specific waiver

EMA-000770-PIP02-11

Scope of the application

Active substance(s):

Esketamine (hydrochloride)

Condition(s):

Treatment of acute inner ear tinnitus

Pharmaceutical form(s):

Gel for injection

Route(s) of administration:

Intratympanic use

Name/corporate name of the PIP applicant:

Auris Medical Limited

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Auris Medical Limited submitted to the European Medicines Agency on 8 August 2011 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

The procedure started on 14 September 2011.

A meeting with the Paediatric Committee took place on 9 November 2011.



Opinion

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to grant a product-specific waiver for all subsets of the paediatric population and the above mentioned condition(s) 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 grounds for the granting of the waiver are set out in Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex and appendix.

London, 11 November 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Treatment of acute inner ear tinnitus

The waiver applies to:

- all subsets of the paediatric population from birth to less than 14 years of age;
- for gel for injection, intratympanic use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

The waiver applies to:

- all subsets of the paediatric population from 14 years to less than 18 years of age;
- for gel for injection, intratympanic use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.