



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/114799/2013

European Medicines Agency decision

P/0070/2013

of 26 March 2013

on the granting of a product specific waiver for hexaminolevulinate (Hexvix), (EMEA-001245-PIP01-11)
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 hexaminolevulinate (Hexvix), (EMA-001245-PIP01-11) 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 Photocure ASA on 5 November 2012 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 8 February 2013 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 hexaminolevulinate (Hexvix), vaginal ointment, powder and solvent for intravesical solution, vaginal use, intravesical 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 Photocure ASA, 4 Hoffsvæien, 0275 – Oslo, Norway.

Done at London, 26 March 2013

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



EUROPEAN MEDICINES AGENCY
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EMA/PDCO/746432/2012

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

EMA-001245-PIP01-11

Scope of the application

Active substance(s):

Hexaminolevulinate

Invented name:

Hexvix

Condition(s):

Treatment of cervical dysplasia

Diagnosis of bladder cancer

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Vaginal ointment

Powder and solvent for intravesical solution

Route(s) of administration:

Vaginal use

Intravesical use

Name / corporate name of the PIP applicant:

Photocure ASA

Information about the authorised medicinal product:

See Annex II



Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Photocure ASA submitted to the European Medicines Agency on 5 November 2012 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 12 December 2012.

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)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population and 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 Norwegian Paediatric Committee member agrees 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 annexes and appendix.

London, 8 February 2013

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 cervical dysplasia

The waiver applies to:

- all boys and pre-menarchal girls;
- for vaginal ointment, vaginal 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).

And to:

- post-menarchal girls;
- for vaginal ointment, vaginal use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

1.2. Condition: diagnosis of bladder cancer

The waiver applies to:

- all paediatric population;
- for powder and solvent for intravesical solution;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not exist in the paediatric population.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Diagnosis of bladder cancer

Authorised indication:

Detection of bladder cancer, such as carcinoma in situ, in patients with known bladder cancer or high suspicion of bladder cancer, based on e.g., screening cystoscopy or positive urine cytology.

Authorised pharmaceutical formulation(s):

Powder for solution

Authorised route(s) of administration:

Intravesical use