



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/494466/2023

European Medicines Agency decision P/0486/2023

of 30 November 2023

on the granting of a product specific waiver for glyceryl trinitrate (Nitromint), (EMEA-003479-PIP01-23) 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 glyceryl trinitrate (Nitromint), (EMA-003479-PIP01-23) 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency²,

Having regard to the application submitted by Egis Pharmaceuticals PLC. on 30 June 2023 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 13 October 2023 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.

Has adopted this decision:

Article 1

A waiver for glyceryl trinitrate (Nitromint), sublingual spray, sublingual 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 Egis Pharmaceuticals PLC, Kereszturi ut 30-38, 1106 – Budapest, Hungary.

¹ OJ L 378, 27.12.2006, p.1, as amended.

² OJ L 136, 30.4.2004, p. 1, as amended.



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EMA/PDCO/344848/2023
Amsterdam, 13 October 2023

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

EMA-003479-PIP01-23

Scope of the application

Active substance(s):

Glyceryl trinitrate

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of ischaemic coronary artery disorders

Treatment of heart failure

Prevention of cardiac and vascular procedural complications

Pharmaceutical form(s):

Sublingual spray

Route(s) of administration:

Sublingual use

Name/corporate name of the PIP applicant:

Egis Pharmaceuticals PLC.

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Egis Pharmaceuticals PLC. submitted to the European Medicines Agency on 30 June 2023 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 August 2023.



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 Paediatric Committee member of Norway 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.

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Treatment of ischaemic coronary artery disorders

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- sublingual spray, sublingual use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.2. Condition:

Treatment of heart failure

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- sublingual spray, sublingual use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.3. Condition:

Prevention of cardiac and vascular procedural complications

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- sublingual spray, sublingual use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Treatment of ischaemic coronary artery disorders

Authorised indication(s):

- Treatment of acute anginal attack in adult patients
 - Invented name(s): Nitromint
 - Authorised pharmaceutical form(s): Sublingual spray, solution
 - Authorised route(s) of administration: Sublingual use
 - Authorised via national procedure in Hungary, Czech Republic, Lithuania, Latvia, Romania and Slovakia
- Prevention of anginal attack with application prior to the physical or mental stress expected to provoke an attack according to the experiences in adult patients
 - Invented name(s): Nitromint
 - Authorised pharmaceutical form(s): Sublingual spray, solution
 - Authorised route(s) of administration: Sublingual use
 - Authorised via national procedure in Hungary, Czech Republic, Lithuania, Latvia, Romania and Slovakia
- Reduction of filling pressure in acute myocardial infarction in adult patients
 - Invented name(s): Nitromint
 - Authorised pharmaceutical form(s): Sublingual spray, solution
 - Authorised route(s) of administration: Sublingual use
 - Authorised via national procedure in Hungary, Czech Republic, Lithuania, Latvia, Romania and Slovakia

2. Treatment of heart failure signs and symptoms

- Adjuvant treatment of the emergency cases of acute left ventricular insufficiency (cardiac asthma) in adult patients
 - Invented name(s): Nitromint
 - Authorised pharmaceutical form(s): Sublingual spray, solution
 - Authorised route(s) of administration: Sublingual use
 - Authorised via national procedure in Hungary, Czech Republic, Lithuania, Latvia, Romania and Slovakia

3. Prevention of cardiac and vascular procedural complications

- Prevention of coronary spasm induced by cardiac catheterisation during coronarography in adult patients
 - Invented name(s): Nitromint

- Authorised pharmaceutical form(s): Sublingual spray, solution
- Authorised route(s) of administration: Sublingual use
- Authorised via national procedure in Hungary, Czech Republic, Lithuania, Latvia, Romania and Slovakia