EMA/114310/2020

European Medicines Agency decision

P/0079/2020

of 18 March 2020

on the granting of a product specific waiver for rosuvastatin / ezetimibe (Rosuvastatin/Ezetimibe Elpen and associated names), (EMEA-002257-PIP02-19) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Only the English text is authentic.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

European Medicines Agency decision

P/0079/2020

of 18 March 2020

on the granting of a product specific waiver for rosuvastatin / ezetimibe (Rosuvastatin/Ezetimibe Elpen and associated names), (EMEA-002257-PIP02-19) 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 application submitted by ELPEN Pharmaceutical Co. Inc. on 25 October 2019 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 31 January 2020 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 rosuvastatin / ezetimibe (Rosuvastatin/Ezetimibe Elpen and associated names), film-coated tablet, oral 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 ELPEN Pharmaceutical Co. Inc., 95 Marathonos Ave., GR-19009 - Pikermi, Attica, Greece.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

EMA/PDCO/631371/2019
Amsterdam, 31 January 2020

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

EMEA-002257-PIP02-19

Scope of the application

Active substance(s):

Rosuvastatin / ezetimibe

Invented name:

Rosuvastatin/Ezetimibe Elpen and associated names

Condition(s):

Prevention of cardiovascular events

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

ELPEN Pharmaceutical Co. Inc.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, ELPEN Pharmaceutical Co. Inc. submitted to the European Medicines Agency on 25 October 2019 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 3 December 2019.

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 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.

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:

Prevention of cardiovascular events

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- film-coated tablet, oral 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

Condition(s) and authorised indication(s):

1. Treatment of hypercholesterolaemia

Authorised indication:

Treatment of primary hypercholesterolemia as substitution therapy in adult patients adequately controlled with the individual substances given concurrently at the same dose level as in the fixed dose combination

Authorised pharmaceutical form(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use