EMA/421220/2018

European Medicines Agency decision

P/0206/2018

of 19 July 2018

on the granting of a product specific waiver for bilastine (Bilaxten and associated names), (EMEA-000347-PIP03-18) 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 bilastine (Bilaxten and associated names), (EMEA-000347-PIP03-18) 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 Faes Farma, S.A. on 22 March 2018 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 1 June 2018 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 bilastine (Bilaxten and associated names), orodispersible film, 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 Faes Farma, S.A., Maximo Aguirre 14, 48940 – LEIOA, Spain.

EMA/PDCO/215091/2018
London, 1 June 2018

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

EMEA-000347-PIP03-18

Scope of the application

Active substance(s):

Bilastine

Invented name:

Bilaxten and associated names

Condition(s):

Treatment of allergic rhinoconjunctivitis

Treatment of urticaria

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Orodispersible film

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Faes Farma, S.A.

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Faes Farma, S.A. submitted to the European Medicines Agency on 22 March 2018 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 April 2018.

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 conditions 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 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.

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Treatment of allergic rhinoconjunctivitis

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- orodispersible film, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.

1.2. Condition:

Treatment of urticaria

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- orodispersible film, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of allergic rhinoconjunctivitis
2. Treatment of urticaria

Authorised indication(s):

- Symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria in adults and adolescents (12 years of age and over)
- Symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria. Bilaxten and associated names is indicated in children aged 6 to 11 years with a body weight of at least 20 kg.

Authorised pharmaceutical form(s):

Tablet

Oral solution

Orodispersible tablet

Authorised route(s) of administration:

Oral use