EMA/816627/2018

European Medicines Agency decision

P/0009/2019

of 3 January 2019

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for bilastine (Bilaxten and associated names), (EMEA-000347-PIP02-16) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Contact EMA www.ema.europa.eu/contact

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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 20 October 2017 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 November 2018, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 of said Regulation,

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

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

(4) 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 paediatric investigation plan for bilastine (Bilaxten and associated names), eye drops, solution, ocular 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 agreed.

Article 2

A deferral for bilastine (Bilaxten and associated names), eye drops, solution, ocular 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 3

A waiver for bilastine (Bilaxten and associated names), eye drops, solution, ocular 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 4

This decision covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/88/2009 issued on 18 May 2009, including subsequent modifications thereof.

Article 5

This decision is addressed to Faes Farma S.A. Maximo Aguirre, 14, 48940 – Leioa, Spain.

EMA/PDCO/596750/2018
London, 16 November 2018

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMEA-000347-PIP02-16

Scope of the application

Active substance(s):

Bilastine

Invented name:

Bilaxten and associated names

Condition(s):

Treatment of allergic conjunctivitis

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Eye drops, solution

Route(s) of administration:

Ocular use

Name/corporate name of the PIP applicant:

Faes Farma S.A.

Information about the authorised medicinal product:

See Annex II

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Faes Farma S.A. submitted for agreement to the European Medicines Agency on 20 October 2017 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 28 November 2017.

Supplementary information was provided by the applicant on 1 August 2018. The applicant proposed modifications to the paediatric investigation plan.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded 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.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the 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

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition:

Treatment of allergic conjunctivitis

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- eye drops, solution, ocular 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).

2. Paediatric investigation plan

2.1. Condition

Treatment of allergic conjunctivitis

2.1.1. Indication(s) targeted by the PIP

Symptomatic treatment of allergic conjunctivitis (seasonal and perennial) in children 2 years and older

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 2 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Eye drops, solution

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	1	**Study 1** Double-blind, randomised, placebo-controlled, parallel-group trial to evaluate safety, tolerability and efficacy of bilastine ophthalmic solution 0.6% in children from 2 to less than 18 years of age with seasonal (SAC) or perennial allergic conjunctivitis (PAC)
Extrapolation, modelling and simulation	2	**Study 2** Simulation of bilastine systemic plasma profiles in children from 2 to

studies		less than 18 years of age after ocular administration of bilastine, based on the systemic absorption observed for ophthalmic bilastine in adults and on the population systemic PK parameters previously estimated in children after oral bilastine **Study 3** Analysis of existing data on ocular bilastine in the treatment of allergic conjunctivitis in children from 2 to less than 18 years of age
Other studies	0	Not applicable
Other measures	0	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By May 2021
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of allergic rhinoconjunctivitis

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 in children aged 6 to 11 years with a body weight of at least 20 kg

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 in children aged 6 to 11 years with a body weight of at least 20 kg

Authorised pharmaceutical form(s):

Tablet

Orodispersible tablet

Oral solution

Authorised route(s) of administration:

Oral use