



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/236606/2023

European Medicines Agency decision P/0209/2023

of 14 June 2023

on the acceptance of a modification of an agreed paediatric investigation plan for bilastine (Bilaxten and associated names), (EMEA-000347-PIP02-16-M05) 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.



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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 726/2004¹,

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 European Medicines Agency's decision P/0009/2019 issued on 3 January 2019, the decision P/0408/2019 issued on 4 December 2019, the decision P/0466/2020 issued on 1 December 2020, the decision P/0526/2021 issued on 3 December 2021 and the decision P/0506/2022 issued on 2 December 2022,

Having regard to the application submitted by Faes Farma S.A. on 21 December 2022 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 26 April 2023, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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 acceptance of changes to the agreed paediatric investigation plan and to the deferral.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

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

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for bilastine (Bilaxten and associated names), eye drops, solution, ocular use, including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

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 3

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/56713/2023
Amsterdam, 26 April 2023

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-000347-PIP02-16-M05

Scope of the application

Active substance(s):

Bilastine

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of allergic conjunctivitis

Pharmaceutical form(s):

Eye drops, solution

Route(s) of administration:

Ocular use

Name/corporate name of the PIP applicant:

Faes Farma S.A.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Faes Farma S.A. submitted to the European Medicines Agency on 21 December 2022 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0009/2019 issued on 3 January 2019, the decision P/0408/2019 issued on 4 December 2019, the decision P/0466/2020 issued on 1 December 2020, the decision P/0526/2021 issued on 3 December 2021 and the decision P/0506/2022 issued on 2 December 2022.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 27 February 2023.



Scope of the modification

Some timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:
 - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

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

2. The measures and timelines of the 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 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Eye drops, solution

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	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 years to less than 18 years of age with seasonal (SAC) or perennial allergic conjunctivitis (PAC) (BOFT-0520-PED)
Extrapolation, modelling and simulation studies	Study 2 Simulation of bilastine systemic plasma profiles in children from 2 years to less than 18 years of age after ocular administration of bilastine, based on

	<p>the systemic absorption observed for ophthalmic bilastine in adults and on the population systemic PK parameters previously estimated in children after oral bilastine (M&S-001)</p> <p>Study 3</p> <p>Analysis of existing data on ocular bilastine in the treatment of allergic conjunctivitis in children from 2 years to less than 18 years of age (EXTRAPOL-001)</p>
Other studies	Not applicable
Other measures	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 December 2023
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

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. Bilaxten is indicated in adults and adolescents (12 years of age and over).
- Symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria. Bilaxten is indicated in children aged 6 to 11 years with a body weight of at least 20 kg.
 - Invented name(s): Bilaxten and associated names
 - Authorised pharmaceutical form(s): tablet, orodispersible tablet, oral solution
 - Authorised route(s) of administration: oral use
 - Authorised via decentralised procedure

2. Treatment of urticaria

Authorised indication(s):

- Symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria. Bilaxten is indicated in adults and adolescents (12 years of age and over).
- Symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria. Bilaxten is indicated in children aged 6 to 11 years with a body weight of at least 20 kg.
 - Invented name(s): Bilaxten and associated names
 - Authorised pharmaceutical form(s): tablet, orodispersible tablet, oral solution
 - Authorised route(s) of administration: oral use
 - Authorised via decentralised procedure

3. Treatment of allergic conjunctivitis

Authorised indication(s):

- Treatment of ocular signs and symptoms of seasonal and perennial allergic conjunctivitis. Bilaxten is indicated in adults.
 - Invented name(s): Bilaxten and associated names
 - Authorised pharmaceutical form(s): eye drops solution
 - Authorised route(s) of administration: ocular use
 - Authorised via decentralised procedure