



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-1793589

European Medicines Agency decision

EMA/PE/0000221803

of 6 December 2024

on the refusal of a paediatric investigation plan and on the granting of a waiver for betula pendula pollen extract 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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on the refusal of a paediatric investigation plan and on the granting of a waiver for *betula pendula* pollen extract 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 ROXALL Medicina España S.A. on 8 July 2024 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 October 2024, in accordance with Article 17 of Regulation (EC) No 1901/2006 and of its own motion in accordance with Article 12 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 refusal of a paediatric investigation plan and on the granting of a waiver.
- (2) It is therefore appropriate to adopt a decision refusing a paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision granting a waiver.

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

A paediatric investigation plan for betula pendula pollen extract, 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 refused.

Article 2

A product-specific waiver for betula pendula pollen extract, 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

This decision is addressed to ROXALL Medicina España S.A. Parque Científico y Tecnológico de Bizkaia, Edificio 401, 48170 Zamudio Vizcaya, Spain.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/464121/2008

Amsterdam, 18 October 2024

Opinion of the Paediatric Committee on the refusal of a Paediatric Investigation Plan and on the granting of a product-specific waiver

EMA/PE/0000221803

Scope of the application

Active substance(s):

Betula pendula pollen extract

Invented name and authorisation status:

See Annex II

Condition(s):

Diagnosis of birch pollen allergy

Pharmaceutical form(s):

Solution for skin-prick test

Route(s) of administration:

Intraepidermal use

Name/corporate name of the PIP applicant:

ROXALL Medicina España S.A.

Basis for opinion

Pursuant to Betula pendula pollen extract of Regulation (EC) No 1901/2006 as amended, ROXALL Medicina España S.A. submitted for agreement to the European Medicines Agency on 8 July 2024 an application for a paediatric investigation plan for the above-mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 19 August 2024.



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 refuse the paediatric investigation plan in accordance with Article 17(1) of said Regulation as the measures and the timelines are not appropriate to ensure the generation of the necessary data determining the conditions in which the medicinal product may be used to treat the paediatric population or some subsets, nor to adapt a paediatric formulation, or do not bring the expected significant therapeutic benefit;
 - to grant a product-specific waiver for all subsets of the paediatric population of its own motion in accordance with Article 12 of said Regulation and concluded 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:

Diagnosis of birch pollen allergy

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- for solution for skin-prick test, intraepidermal use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.