

EMA/253298/2023

European Medicines Agency decision P/0207/2023

of 14 June 2023

on the refusal of a paediatric investigation plan and on the granting of a waiver for xylometazoline hydrochloride / sodium hyaluronate (EMEA-003387-PIP01-22) 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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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 Jadran galenski laboratorij d.d. on 31 December 2022 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 26 April 2023, 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 xylometazoline hydrochloride / sodium hyaluronate, nasal spray, solution, nasal 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 refused.

Article 2

A product-specific waiver for xylometazoline hydrochloride / sodium hyaluronate, nasal spray, solution, nasal 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

This decision is addressed to Jadran galenski laboratorij, Svilno 20, 51000 – Rijeka, Croatia.

EMA/PDCO/181166/2023
Amsterdam, 26 April 2023

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

EMA-003387-PIP01-22

Scope of the application

Active substance(s):

Xylometazoline hydrochloride / sodium hyaluronate

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of acute rhinosinusitis

Pharmaceutical form(s):

Nasal spray, solution

Route(s) of administration:

Nasal use

Name/corporate name of the PIP applicant:

Jadran galenski laboratorij d.d.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Jadran galenski laboratorij d.d. submitted for agreement to the European Medicines Agency on 31 December 2022 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 27 February 2023.

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 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)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population and 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:

Treatment of acute rhinosinusitis

The waiver applies to:

- The paediatric population from birth to less than 2 years of age;
- for nasal spray, solution, nasal use;
- on the grounds that the specific medicinal product is likely to be unsafe.

The waiver applies to:

- The paediatric population from 2 years to less than 18 years of age;
- for nasal spray, solution, nasal 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

Information provided by the applicant:

The product is not authorised anywhere in the European Community.