



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/105459/2024

European Medicines Agency decision P/0132/2024

of 12 April 2024

on the granting of a product specific waiver for netupitant / palonosetron (Akynzeo), (EMA-001198-PIP04-23) 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 Helsinn Birex Pharmaceuticals Limited on 21 November 2023 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 23 February 2024 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.

Has adopted this decision:

Article 1

A waiver for netupitant / palonosetron (Akynzeo), oral suspension, 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 Helsinn Birex Pharmaceuticals Limited, Damastown, Mulhuddart, Dublin 15 – Dublin, Ireland.

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

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

EMA/PDCO/543467/2023
Amsterdam, 23 February 2024

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

EMA-001198-PIP04-23

Scope of the application

Active substance(s):

Netupitant / palonosetron

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of chemotherapy-induced nausea and vomiting

Pharmaceutical form(s):

Oral suspension

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Helsinn Birex Pharmaceuticals Limited

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Helsinn Birex Pharmaceuticals Limited submitted to the European Medicines Agency on 21 November 2023 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 January 2024.

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 condition(s) 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:

Prevention of chemotherapy-induced nausea and vomiting

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- oral suspension, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Prevention of chemotherapy-induced nausea and vomiting

Authorised indication(s):

- Prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy.
 - Invented name(s): Akynzeo
 - Authorised pharmaceutical form(s): hard capsule, powder for concentrate for solution for infusion, concentrate for solution for infusion
 - Authorised route(s) of administration: oral, intravenous
 - Authorised via centralised procedure.
- Prevention of acute and delayed nausea and vomiting associated with moderately emetogenic cancer chemotherapy.
 - Invented name(s): Akynzeo
 - Authorised pharmaceutical form(s): hard capsule, powder for concentrate for solution for infusion, concentrate for solution for infusion
 - Authorised route(s) of administration: oral, intravenous
 - Authorised via centralised procedure.