EMA/144829/2021

European Medicines Agency decision

P/0075/2021

of 17 March 2021

on the granting of a product specific waiver for canakinumab (Ilaris), (EMEA-000060-PIP09-20) 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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on the granting of a product specific waiver for canakinumab (Ilaris), (EMEA-000060-PIP09-20) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the CouncilThe 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 Novartis Europharm Limited on 22 October 2020 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 29 January 2021 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 canakinumab (Ilaris), powder for solution for injection, solution for injection, subcutaneous 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 Novartis Europharm Limited, Vista Building, Elm Park, Merrion Road, D04 A9N6 - Dublin 4, Ireland.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

EMA/PDCO/611958/2020
Amsterdam, 29 January 2021

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

EMEA-000060-PIP09-20

Scope of the application

Active substance(s):

Canakinumab

Invented name:

Ilaris

Condition(s):

Treatment of Schnitzler syndrome

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for solution for injection

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Novartis Europharm Limited

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Limited submitted to the European Medicines Agency on 22 October 2020 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 1 December 2020.

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)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended occurs only in adult populations.

   The Norwegian Paediatric Committee member 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 Schnitzler syndrome

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- powder for solution for injection and solution for injection, subcutaneous 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).

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of cryopyrin associated periodic syndromes (CAPS) including: Familial cold autoinflammatory syndrome (FCAS) / familial cold urticaria (FCU), Muckle-Wells syndrome (MWS), Neonatal-onset multisystem inflammatory disease (NOMID) / chronic infantile neurological, cutaneous, articular syndrome (CINCA) (covered by EMEA-000060-PIP01-07)

Authorised indication(s):

Canakinumab is indicated for the treatment of the following autoinflammatory periodic fever syndromes in adults, adolescents and children aged 2 years and older:

- cryopyrin-associated periodic syndromes (CAPS), including Muckle-Wells syndrome (MWS), Neonatal-onset multisystem inflammatory disease (NOMID) / chronic infantile neurological, cutaneous, articular syndrome (CINCA) and Severe forms of familial cold autoinflammatory syndrome (FCAS) / familial cold urticaria (FCU) presenting with signs and symptoms beyond cold-induced urticarial skin rash

2. Treatment of tumour necrosis factor receptor associated periodic syndrome (covered by EMEA-000060-PIP05-14)

Authorised indication(s):

Canakinumab is indicated for the treatment of the following autoinflammatory periodic fever syndromes in adults, adolescents and children aged 2 years and older:

- Ilaris is indicated for the treatment of tumour necrosis factor (TNF) receptor associated periodic syndrome (TRAPS)

3. Treatment of hyperimmunoglobulin D syndrome (covered by EMEA-000060-PIP04-14)

Authorised indication(s):

Canakinumab is indicated for the treatment of the following autoinflammatory periodic fever syndromes in adults, adolescents and children aged 2 years and older:

- Ilaris is indicated for the treatment of hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD)

4. Treatment of familial Mediterranean fever (covered by EMEA-000060-PIP04-14)

Authorised indication(s):

Canakinumab is indicated for the treatment of the following autoinflammatory periodic fever syndromes in adults, adolescents and children aged 2 years and older:

- Ilaris is indicated for the treatment of Familial Mediterranean Fever (FMF). Ilaris should be given in combination with colchicine, if appropriate

5. Treatment of juvenile idiopathic arthritis (covered by EMEA-000060-PIP02-08)

Authorised indication(s):

- Ilaris is indicated for the treatment of active Still's disease including adult-onset Still's disease (AOSD) and systemic juvenile idiopathic arthritis (SJIA) in patients aged 2 years and older who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Ilaris can be given as monotherapy or in combination with methotrexate

6. Treatment of gout (covered by EMEA-000060-PIP07-19)

Authorised indication(s):

- Ilaris is indicated for the symptomatic treatment of adult patients with frequent gouty arthritis attacks (at least 3 attacks in the previous 12 months) in whom non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate.

Authorised pharmaceutical form(s):

Powder for solution for injection

Solution for injection

Authorised route(s) of administration:

Subcutaneous use.