



European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 20 April 2009

**on the agreement of a Paediatric Investigation Plan for mercaptopurine monohydrate
(EMEA-000350-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European
Parliament and of the Council as amended**

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

*DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of
Regulation (EC) No 1901/2006, as amended.*

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Parliament and of the Council as amended**

THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency²,

Having regard to the application submitted by Nova Laboratories Limited on 22 August 2008 under Article 15 of Regulation (EC) No 1901/2006 as amended,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 6 March 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended,

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

- (1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a Paediatric Investigation Plan,
- (2) It is therefore appropriate to adopt a Decision granting a Paediatric Investigation Plan.

¹ OJ L 378, 27.12.2006, p.1

² OJ L 136, 30.4.2004, p. 1

HAS ADOPTED THIS DECISION:

Article 1

A Paediatric Investigation Plan for mercaptopurine monohydrate, 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 agreed.

Article 2

This decision is addressed to Nova Laboratories Limited, Martin House, Gloucester Crescent, Wingston, Leicester, LE18 4YL, United Kingdom.

Done at London, 20 April 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)



**OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF
A PAEDIATRIC INVESTIGATION PLAN**

Scope of the application

Active substance(s):

Mercaptopurine monohydrate

Condition:

Acute lymphoblastic leukaemia

Pharmaceutical form:

Oral Suspension

Route of administration:

Oral use

Name/corporate name of the PIP applicant:

Nova Laboratories Limited

Basis for opinion

Pursuant to Article 15 of Regulation (EC) No 1901/2006 as amended, Nova Laboratories Limited submitted for agreement to the EMA on 22 August 2008 an application for a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 25 September 2008.

Supplementary information was provided by the applicant on 23 December 2008

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 agree the paediatric investigation plan in accordance with Article 18 of said Regulation,

The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annex(es) and appendix.

London, 6 March 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

THE MEASURES AND TIMELINES OF THE AGREED PAEDIATRIC INVESTIGATION PLAN

A. CONDITION

Acute lymphoblastic leukaemia

B. WAIVER

Not applicable.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Acute lymphoblastic leukaemia

- **Proposed PIP indication**

Treatment of acute lymphoblastic leukaemia in children from 0 to less than 18 years.

- **Subset(s) of the paediatric population concerned by the paediatric development**

From 0 to less than 18 years.

- **Formulation**

Oral suspension

- **Studies**

Area	Number of studies	Description
Quality	1	Studies to establish the minimum quantity of preservatives (75%, 50% and 25% of the established preservative concentrations) necessary for maintaining acceptable microbial quality of the oral formulation.
Clinical	1	Open-label, single dose, single-centre, randomized, crossover trial to assess the bioequivalence of oral mercaptopurine suspension to the tablet formulation in adults.

Measures to address long term follow-up of potential safety issues or efficacy in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2009
Deferral for some or all studies contained in the paediatric investigation plan:	No