



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/791551/2016

European Medicines Agency decision

P/0360/2016

of 21 December 2016

on the agreement of a paediatric investigation plan and on the granting of a waiver for octenidine (dihydrochloride) (EMEA-001384-PIP01-12) 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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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 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 Schülke & Mayr GmbH on 10 December 2012 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 11 November 2016, in accordance with Article 18 of Regulation (EC) No 1901/2006 and Article 13 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 agreement of a paediatric investigation plan and on the granting of a waiver.
- (2) It is therefore appropriate to adopt a decision agreeing 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.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for octenidine (dihydrochloride), cutaneous solution, cutaneous 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

A waiver for octenidine (dihydrochloride), cutaneous solution, cutaneous 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 Schülke & Mayr GmbH, Robert-Koch-Str 2, 22851 – Norderstedt, Germany.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/584295/2016
London, 11 November 2016

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a waiver

EMA-001384-PIP01-12

Scope of the application

Active substance(s):

Octenidine (dihydrochloride)

Condition(s):

Skin disinfection

Pharmaceutical form(s):

Cutaneous solution

Route(s) of administration:

Cutaneous use

Name/corporate name of the PIP applicant:

Schülke & Mayr GmbH

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Schülke & Mayr GmbH submitted for agreement to the European Medicines Agency on 10 December 2012 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 16 January 2013.

Supplementary information was provided by the applicant on 22 August 2016. The applicant proposed modifications to the paediatric investigation plan.



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;
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 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 Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition

Skin disinfection

The waiver applies to:

- the paediatric population from 2 months to less than 18 years of age;
- cutaneous solution, for cutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition

Skin disinfection

2.1.1. Indication(s) targeted by the PIP

Disinfection of intact external skin for example prior to surgery, injections, punctures, blood-taking catheterisations in premature neonates, mature neonates and infants less than 2 months of age

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 2 months of age

2.1.3. Pharmaceutical form(s)

Cutaneous solution

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1 Development of a sterile solution containing octenidine as active ingredient for skin antisepsis of premature neonates, mature neonates and infants less than 2 months of age
Non-clinical studies	1	Study 2 Evaluation of the efficacy of plain octenidine dihydrochloride against various pathogens commonly associated with catheter related infections (OCT-PRETERM-IN-VITRO-02)

Clinical studies	3	<p>Study 3</p> <p>Observer-blinded, cross-over, dose / exposure time finding study to identify a concentration of topically applied octenidine dihydrochloride solution in an exposure time that is non-inferior to 70% isopropanol and 0.05% chlorhexidine solution in terms of skin antiseptics (OCT-PRETERM-01)</p> <p>Study 4</p> <p>Observer blinded pharmacokinetics and safety study of octenidine (specifically its systemic exposure after topical administration to healthy skin) in term neonates and infants (OCT-NEONATE-01)</p> <p>Study 5</p> <p>Observer-blinded, active-comparator-controlled, multicenter trial to evaluate the safety/tolerability, efficacy of octenidine dihydrochloride cutaneous solution in skin disinfection on premature neonates (OCT-PRETERM-02)</p>
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2020
Deferral for one or more measures contained in the paediatric investigation plan:	No