

**Rapporteur's  
Public Paediatric Assessment Report  
for paediatric studies submitted in accordance  
with Article 46 of Regulation (EC) No1901/2006, as amended**

**Elidel cream 1%  
pimecrolimus**

**DK/W/007/pdWS/002**

**Marketing Authorisation Holder:  
Novartis Healthcare A/S**

<b>Rapporteur:</b>	Denmark
<b>Start of the procedure (day 0):</b>	26.05.2010
<b>End of Procedure:</b>	24.08.2010
<b>Date of this report:</b>	28.10.2010

## ADMINISTRATIVE INFORMATION

Invented name of the medicinal product:	Elidel
INN (or common name) of the active substance(s):	Pimecrolimus
MAH:	Novartis Healthcare A/S
Currently approved Indication(s)	<p>Treatment of patients aged 2 years and over with mild or moderate atopic dermatitis where treatment with topical corticosteroids is either inadvisable or not possible. This may include:</p> <ul style="list-style-type: none"> <li>• Intolerance to topical corticosteroids</li> <li>• Lack of effect of topical corticosteroids</li> <li>• Use on the face and neck where prolonged intermittent treatment with topical corticosteroids may be inappropriate</li> </ul>
Pharmaco-therapeutic group (ATC Code):	D11AX15
Pharmaceutical form(s) and strength(s):	Crème 1%

# INDEX

## **I. Executive Summary**

## **II. Recommendation**

## **III. Introduction**

## **IV. Scientific Discussion**

- IV.1. Information on the pharmaceutical formulation used in the clinical studies**
- IV.2. Clinical aspects**

## **V. Rapporteur's overall conclusion and recommendation**

## **I. EXECUTIVE SUMMARY**

No SmPC and PL changes are proposed.

## **II. RECOMMENDATION**

The MAH has submitted efficacy and safety data from an open-label pharmacovigilance study in which children with mild or moderate atopic dermatitis received 6 weeks of treatment with Elidel cream 1% according to approved SmPC posology. The study results confirmed both the efficacy and the safety of Elidel cream 1% for short-term therapy of atopic dermatitis. No SmPC and PL changes are proposed.

## **III. INTRODUCTION**

On 10<sup>th</sup> May 2010 the MAH submitted a completed paediatric study for a six-week observational study to evaluate efficacy and tolerability of Elidel (pimecrolimus) cream 1% in patients with mild or moderate atopic dermatitis, in accordance with Article 46 of Regulation (EC) No1901/2006, as amended, on medicinal products for paediatric use.

A short critical expert overview has also been provided.

The MAH stated that the submitted paediatric study does not influence the benefit risk for Elidel (pimecrolimus) cream 1% and that there is no consequential regulatory action.

## **IV. SCIENTIFIC DISCUSSION**

### **IV.1 Information on the pharmaceutical formulation used in the study**

The marketed formulation of Elidel cream 1% was used in the clinical trial. Elidel cream 1% is approved for treatment of patients aged 2 years and over with mild or moderate atopic dermatitis, where treatment with topical corticosteroids is either inadvisable or not possible.

Elidel cream 1% may be used for short term treatment or intermittently in the long term for prevention of progression to flares.

### **IV.2 Clinical aspects**

#### **1. Introduction**

The MAH has submitted one paediatric study entitled:

A six-week observational study to evaluate the efficacy and tolerability of Elidel (pimecrolimus) cream 1% in patients with mild or moderate atopic dermatitis (AD) (Study CASM981CSA04).

#### **2. Clinical study**

A six-week observational study to evaluate the efficacy and tolerability of Elidel (pimecrolimus) cream 1% in patients with mild or moderate atopic dermatitis (AD) (Study CASM981CSA04).

#### **➤ Description**

## ➤ **Methods**

- Objectives

To evaluate the efficacy and safety of Elidel cream 1% in short-term treatment of mild or moderate AD in children.

- Study design

Open-label, uncontrolled study.

- Study population /Sample size

Children 2 years and over with a diagnosis of mild or moderate AD. A total of 1440 patients were recruited and included in the safety analysis out of which 1402 patients were eligible for efficacy evaluation at the end of the study.

- Treatment

Elidel cream 1% applied twice daily for 6 weeks.

- Outcomes/endpoints

The efficacy variables were: Investigator Global Assessment (IGA) score (whole body and face) and severity assessment of pruritus. Adverse events were recorded in case record forms. The evaluations were performed at baseline, week 1 and at the end of the study. Laboratory evaluations were not performed.

- Statistical Methods

X<sup>2</sup> test and 2-tailed, paired t-test was used to assess the statistical significances in the efficacy and safety variables. Responder's rate was analyzed using logistic regression.

## ➤ **Results**

- Recruitment/ Number analysed

A total of 1440 children were recruited and included in the safety analysis out of which 1402 children were eligible for the efficacy evaluation at the study conclusion.

- Baseline data

A total of 623 (45%) children were in the age group 2-5 years, 367 (26%) in the age group 5-10 years and 412 (29%) > 10 years of age. At enrolment 29% of the children (n=402) had mild AD while 59% of the children (n=827) had moderate AD.

- Efficacy results

IGA whole body score decreased from 2.56 at visit 1 to 0.33 at week 6 (87% reduction from baseline). IGA face score decreased from 2.32 at visit 1 to 0.22 at week 6 (90 % reduction from baseline). Pruritus severity assessment (PSA) decreased on a 4-point scale from 1.84 at visit 1 to 0.15 at week 6 (89% reduction form baseline).

- Safety results

Thirty one children (2%) experienced adverse events (AE) during the study. Two of the 31 children discontinued due to AE, one because of burning sensation and the other because of contact dermatitis. No serious AE were recorded throughout the 6 week study period. The reported AE were all of local nature.

### **3. Discussion on clinical aspects**

The results of the study support that Elidel cream 1% is well tolerated and effective in treatment of mild to moderate atopic dermatitis in children age 2 years and over.

## **V. RAPPORTEUR'S OVERALL CONCLUSION AND RECOMMENDATION**

### ➤ **Overall conclusion**

It is the opinion of the assessor that the submitted study support the short-term tolerability and efficacy of Elidel cream 1% in children aged 2 years and over with mild to moderate atopic dermatitis. The efficacy and safety data from study CASM981CSA04 are consistent with previously presented and published data on Elidel cream 1% and no proposed changed to existing SmPC are needed.

### ➤ **Recommendation**

No further action is required.