

**Public 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/003**

**Marketing Authorisation Holder: Novartis**

<b>Rapporteur:</b>	Denmark
<b>Finalisation procedure (day 90):</b>	5/4-2011
<b>Date of finalisation of PAR</b>	27/4-2011

## 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)	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: <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):	Crema 1 %

## **I. EXECUTIVE SUMMARY**

No SmPC and PL changes are proposed.

## **II. RECOMMENDATION**

The Applicant has submitted efficacy and safety data from an open label 6-week observational study in children with mild or moderate atopic dermatitis treated with Elidel (pimecrolimus) cream 1% twice daily. As the study confirms the short-term efficacy and safety of Elidel cream 1% in children with mild to moderate dermatitis, no changes to existing SPC are proposed.

## **III. INTRODUCTION**

On December 16<sup>th</sup>, the MAH submitted a completed paediatric study for Elidel, 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 and that there is no consequential regulatory action.

## **IV. SCIENTIFIC DISCUSSION**

The efficacy and safety of Elidel in the treatment of atopic dermatitis (AD) have been demonstrated in well controlled clinical trials in all age ranges and all disease severities.

The Applicant has submitted the results from an open-label 6 weeks study assessing the efficacy and safety of Elidel (pimecrolimus) cream 1% in children (> 2 years of age) entitled:

A six-week observational study to evaluate the efficacy and tolerability of Elidel (pimecrolimus) cream 1% in patients with mild to moderate atopic dermatitis (CASM 981 CS05). The study was conducted in Saudi Arabia.

In addition the Applicant has submitted a critical Expert overview.

### **Clinical study**

#### **Efficacy**

The efficacy variables were: An improvement in Investigator Global Assessment (IGA) score (whole body, face) and severity assessment of pruritus. Adverse events were recorded during the study. Evaluations were performed at baseline (visit 1) week 1 (visit 2) and at the end of the study (visit 3).

The observation period was 6 weeks.

A total of 1437 children were included of which 1391 completed the study. Only 3 and 1 children withdrew to lack of efficacy and adverse events, respectively.

At baseline 38% of children (n=527) had mild atopic dermatitis (IGA scale whole body = 1 or 2), while 35% of children had moderate atopic dermatitis (IGA scale whole body = 3). Twelve (0.8%) children had severe atopic dermatitis (IGA scale whole body = 4). One hundred thirty three (9%) children had only facial atopic dermatitis.

The mean IGA whole body score decreased from 2.38 at visit 1 to 0.22 at visit 3 (91% reduction from baseline).

The mean IGA face score decreased from 1.97 at visit 1 to 0.13 at visit 3 (93% reduction for baseline). The mean pruritus severity assessment 4-scale decreased from 1.78 at visit 1 to 0.11 at visit 3 (94% reduction from baseline).

#### **SAFETY**

Adverse events with skin irritation and itching in 10 children were considered to be related to the use of Elidel cream. No serious AE were reported.

## **V. MEMBER STATES OVERALL CONCLUSION AND RECOMMENDATION**

### **➤ Overall conclusion**

The results of the study CASM981CSA05 confirm the clinical efficacy and safety of Elidel (pimecrolimus) cream 1% in children with mild to moderate atopic dermatitis.

No changes to existing SPC are proposed.

### **➤ Recommendation**

No further action required.