

Educational Material

Important Safety Information on the appropriate use of *ELIDEL*[®] (pimecrolimus cream 10 mg/g)

Adverse events should be reported to the following:

ADR reporting mailbox:

PV.Mena@mylan.com

Saudi Arabia:

The National Pharmacovigilance and Drug Safety Centre (NPC)

Fax: +966-11-205-7662

Toll free phone: 8002490000; E-mail: npc.drug@sfd.gov.sa

Website: www.sfd.gov.sa/npc

MAH contact details: MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg, Germany

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Elidel® is only approved for Atopic Dermatitis

Elidel® can only be used in children of 2 years or older and in adults.



1 What is Elidel®?

Elidel® contains the active ingredient pimecrolimus, a calcineurin inhibitor that binds with high affinity to macrophilin-12 and inhibits the calcium-dependent phosphatase calcineurin. As a consequence, it blocks the synthesis of inflammatory cytokines in T cells.

Elidel® is a steroid free topical treatment for atopic dermatitis.

2 What is the presentation of Elidel®?

Elidel® is a cream; each g contains 10 mg of pimecrolimus.

3 For which indication only is Elidel® approved?

Elidel® is only approved for Atopic Dermatitis.

4 Can Elidel® be used in all severities of Atopic Dermatitis?

No, Elidel® is indicated for the treatment of mild or moderate atopic dermatitis.

5 Can Elidel® be used in children younger than 2 years of age?

No, Elidel® can only be used in children of 2 years or older and in adults.

Elidel® is authorised for the treatment of patients aged 2 years and Over and has been investigated thoroughly in these patient groups. However, comprehensive experience is lacking for children below the age of 2 years. Therefore, the use of Elidel® in patients under 2 years of age is not recommended.

6 When has Elidel® to be applied?

Elidel® treatment should begin at the first appearance of signs and symptoms of atopic dermatitis. Elidel® should only be applied to areas affected with atopic dermatitis.

7 How can Elidel® be used?

Elidel® can be used in the short term for the treatment of the signs and symptoms of atopic eczema and intermittently in the long term for the prevention of progression to flares. Elidel® should be applied thinly to the affected areas twice daily.

8 For how long can Elidel® be used?

Elidel® should be used for as short period as possible during flares of disease. The patient or caregiver should stop using Elidel® when signs and symptoms resolve. Treatment should be intermittent, short-term and not continuous.

Data from clinical studies support intermittent treatment with Elidel® for up to 12 months.

9 When has Elidel® to be stopped?

The patient or caregiver should stop using Elidel® when signs and symptoms resolve.

If no improvement occurs after 6 weeks, or in case of disease exacerbation, Elidel® should be stopped.

10 Can Elidel® be applied under occlusion?

No, it is not recommended.

11 Can Elidel® be used in pregnancy?

Although there is a minimal absorption Elidel® should not be used during pregnancy.

