European Medicines Agency
*Press office*

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# PRESS RELEASE

# EUROPEAN MEDICINES AGENCY RECOMMENDS CAUTIOUS USE OF PROTOPIC/PROTOPY AND ELIDEL

Finalising its safety review of Protopic/Protopy (tacrolimus) and Elidel (pimecrolimus), the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefit associated with the use of these dermatological medicinal products outweigh the risks, but that they should be used with greater caution in order to reduce potential risks of skin cancer and lymphoma as far as possible.

Patients who are using Protopic/Protopy or Elidel should not stop or modify their treatment without consulting their prescribing healthcare professional.

Protopic/Protopy and Elidel are topical medicines used in the treatment of atopic dermatitis (eczema). Following reports of skin cancer and lymphoma in patients who had used these products, the Committee started the safety review for both products in April 2005.

On the basis of the available data, the Committee was unable to conclude whether Protopic/Protopy or Elidel caused the reported cases of skin cancer or lymphoma. The Committee has requested the companies to gather more data on the long-term safety profile to ensure that it remains acceptable.

The Committee recommended changes to the current product information, which aim at raising awareness of patients and prescribers of the potential long term risks associated with the use of these products.

--ENDS--

NOTES:

1. A question and answer document with detailed information about the new prescribing information is available and has been published here.
2. The Product information as adopted by CHMP on 23 March 2006 is available for Protopic, Protopy and Elidel .
3. Protopic/Protopy are centrally authorised medicines. The marketing authorisation holder is Astellas Pharma GmbH. Protopic is marketed in the following EU and EEA Member States: Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Norway, The Netherlands, Poland, Portugal, Spain, Sweden and the United Kingdom. Protopy is not currently marketed in any EU/EEA Member State.
4. Elidel, which is also known as Aregen, Douglan, Ombex, Rizan and Velov, is authorised in a number of Member States through the mutual recognition procedure. The marketing authorisation holder is Novartis. It is marketed in the following EU and EEA Member States: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Hungary, Iceland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, The Netherlands and the United Kingdom.
5. The review procedure for Protopic/Protopy was initiated by the European Commission under Article 18 of Council Regulation (EC) No 2309/93 and finalised under Article 20 of Regulation (EC) No 726/2004. The review procedure for Elidel and associated trade names was initiated by Denmark under Article 31 of the Community Code on medicinal products for human use.

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6. Procedures under Article 20 of Regulation (EC) No 726/2004 (previously Article 18 of Council Regulation (EC) No 2309/83) are initiated in cases where there is a safety concern relating to a centrally authorised product. Procedures under Article 31 of the Community Code on medicinal products for human use are initiated to review medicinal products authorised at Member State level, because of public health concerns.
7. This press release, together with other information about the work of the EMEA, can be found on the EMEA website: http://www.emea.eu.int/

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