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Questions and answers on EMLA cream and associated names (lidocaine 25 mg/g and prilocaine 25 mg/g; cream for topical use)

Outcome of a procedure under Article 30 of Directive 2001/83/EC

On 25 September 2014, the European Medicines Agency completed a review of EMLA cream. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that there is a need to harmonise the prescribing information for EMLA cream in the European Union (EU).

What is EMLA cream?

EMLA cream is a topical (skin) cream that contains the active substances lidocaine and prilocaine. It is used as a local anaesthetic to prevent pain during medical or superficial surgical procedures.

EMLA cream has been nationally authorised in EU Member States since 1984.

The medicine is currently marketed in the following Member States of the EU: Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Latvia, Luxembourg, Malta, Netherlands, Poland, Portugal, Spain, Sweden and United Kingdom, as well as in Iceland and Norway.

The company that markets these medicines is Astra Zeneca.

Why was EMLA cream reviewed?

EMLA cream is authorised in the EU via national procedures. This has led to divergences across Member States in the way the medicine can be used, as seen in differences in the SmPCs (Summary of Product Characteristics), labelling and package leaflets in the countries where the medicine is marketed.

In view of this, on 11 October 2013 the German medicines regulatory agency referred the matter to the CHMP in order to harmonise the marketing authorisations for EMLA cream in the EU.

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What are the conclusions of the CHMP?

The CHMP, in the light of the data submitted and the scientific discussion within the Committee, was of the opinion that the SmPCs, labelling and package leaflets should be harmonised across the EU.

The areas harmonised include:

4.1 Therapeutic indications

After reviewing the available data supporting the medicine's use, the CHMP agreed that EMLA cream can be used for the following:

- topical anaesthesia of the skin in adults and children;
- topical anaesthesia of the genital mucosa in adults and adolescents;
- topical anaesthesia of leg ulcers in adults only.

4.2 Posology and method of administration

Having harmonised the indications, the CHMP also harmonised recommendations on the doses and the duration of application of EMLA cream before different medical or surgical procedures in children, adolescents or adults. In addition, information has been included to explain that studies did not show that EMLA cream is effective at providing adequate pain relief for circumcision (surgical removal of the foreskin).

4.3 Contra-indications

The CHMP agreed that hypersensitivity (allergy) to lidocaine and/or prilocaine or similar local anaesthetics or to any other ingredients in EMLA cream should be the only contraindication.

Other changes

The CHMP also harmonised other sections of the SmPC including sections 4.4 (special warning and precautions for use), 4.6 (fertility, pregnancy and lactation) and 4.8 (side effects). The labelling and package leaflet were also revised in line with the changes to the SmPC.

The amended information to doctors and patients is available here.

The European Commission issued an EU-wide legally binding decision on 28 November 2014.