LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Luxera
(methyl aminolevulinate hydrochloride)

SE/H/1565/01/DC

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Summary Public Assessment Report

Luxera

(methyl aminolevulinate hydrochloride)

Cream, 160 mg/g

This is a summary of the public assessment report (PAR) for Luxera. It explains how Luxera was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Luxera.

For practical information about using Luxera, patients should read the package leaflet or contact their doctor or pharmacist.

What is Luxera and what is it used for?

This medicine is the same as Metvix, which is already authorised. The company that makes Metvix has agreed that its scientific data can be used as a basis for the grant of identical licence for Luxera (informed consent).

How does Luxera work?

Luxera is used in the treatment of pre-cancerous skin lesions on the face and scalp (known as actinic keratoses), which are areas of the skin that have been damaged by sunlight and become rough and scaly.
Damaged skin cells absorb methyl aminolevulinate from the cream and are destroyed by light exposure (known as photodynamic therapy).

How is Luxera used?

The pharmaceutical form of Luxera is cream.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Luxera have been shown in studies?

Luxera is considered identical to previously authorised Metvix, with the same benefits and risks. So no new studies have been provided for Luxera, but reference is made to the studies for Metvix.

What are the possible side effects of Luxera?

For the full list of all side effects reported with Luxera, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Luxera approved?

Since this medicine is the same as Metvix, which is already authorised, no new or unexpected safety concerns arose from this application. Therefore, the Medical Products Agency in Sweden decided that Luxera's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Luxera?

A risk management plan has been developed to ensure that Luxera is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Luxera, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Luxera

The marketing authorisation for Luxera was granted on 2016-07-14 in Sweden.

The full PAR for Luxera can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Luxera, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2016-07.