



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Ameluz (*5-aminolaevulinic acid*)

An overview of Ameluz and why it is authorised in the EU

What is Ameluz and what is it used for?

Ameluz is a medicine used in adults to treat mild to moderate actinic keratoses on the face and scalp as well as the surrounding areas of the skin affected by the condition. Actinic keratoses are skin growths caused by exposure to sunlight, which can lead to skin cancer. It may also be used to treat an area of sun-induced skin damage with multiple actinic keratosis growths (field cancerisation).

Ameluz can also be used in adults to treat certain types of basal cell carcinoma (a type of skin cancer) when it cannot be treated by surgery.

Ameluz contains the active substance 5-aminolaevulinic acid.

How is Ameluz used?

Ameluz is available as a gel (78 mg/g) to be applied to the skin. It can only be obtained with a prescription and should only be given under the supervision of a healthcare professional experienced in using photodynamic therapy. This method of treatment involves applying a source of light to activate the medicine.

Ameluz is applied directly to the skin growths or lesions or to the entire area affected and a red light source is then shone onto the skin. When treating actinic keratosis growths, Ameluz can also be activated by exposure to full daylight.

Single or multiple actinic keratosis growths may be treated in one session, while basal cell carcinoma lesions will need two treatment sessions about one week apart. The state of the growths or lesions should be monitored three months after treatment, and any remaining growths or lesions should be re-treated.

For more information about using Ameluz, see the package leaflet or contact your doctor or pharmacist.

How does Ameluz work?

When Ameluz is applied to the abnormal skin growths or lesions, the active substance in the medicine, 5-aminolaevulinic acid, is absorbed by cells where it acts as a photosensitising agent (a substance that changes when exposed to light of a certain wavelength). When the affected skin is exposed to light,

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the photosensitising agent is activated and reacts with oxygen in the cells to create a highly reactive and toxic type of oxygen. This kills the cells by reacting with and destroying their components, such as proteins and DNA.

What benefits of Ameluz have been shown in studies?

Ameluz was more effective than placebo (a dummy treatment) or a comparator medicine when used in photodynamic therapy to treat actinic keratosis or basal cell carcinoma. The effects of Ameluz were examined in four main studies in patients with actinic keratosis, and in one main study in patients with basal cell carcinoma. The main measure of effectiveness in all studies was the total number of patients whose actinic keratoses or cancer lesions had all cleared up three months after the last treatment.

In the first main study involving 571 patients, Ameluz was compared with placebo and Metvix, a product containing methylaminolaevulinate, used together with a red light for one or two treatment sessions. Actinic keratosis cleared up in 78% (194 out of 248) of patients treated with Ameluz, compared with 64% (158 out of 246) of patients treated with Metvix and 17% (13 out of 76) of patients treated with placebo.

In the second main study involving 122 patients, Ameluz was compared with placebo used together with a red light for one or two treatment sessions. Actinic keratosis cleared up in 66% (53 out of 80) of patients treated with Ameluz, compared with 13% (5 out of 40) of patients treated with placebo.

In the third study involving 87 patients with field cancerisation (an area of sun damage with several actinic keratosis growths), Ameluz was compared with placebo used for one together with a red light or two treatment sessions. The condition cleared up in 91% (50 out of 55) of patients given Ameluz, compared with 22% (7 out of 32) given placebo.

A further study in 52 patients with actinic keratosis found that Ameluz was at least as effective as Metvix at clearing actinic keratosis when used in combination with daylight.

For basal cell carcinoma that cannot be treated surgically, Ameluz was investigated in a study involving 281 patients, in which it was compared with Metvix. Ameluz was at least as effective as Metvix in this study, with cancerous lesions clearing up in 93% (113 out of 121) of patients treated with Ameluz and 92% (101 out of 110) of those treated with the comparator medicine.

What are the risks associated with Ameluz?

The most common side effects with Ameluz (seen in more than 1 patient in 10) are reactions at the site of application, including erythema (reddening of the skin), pain (including burning pain), irritation, itching, oedema (swelling), scab formation, exfoliation (skin peeling), hardening of the skin and paraesthesia (sensations like numbness, tingling, pins and needles). For the full list of side effects reported with Ameluz, see the package leaflet.

Ameluz must not be given to people who are hypersensitive (allergic) to 5-aminolaevulinic acid, porphyrins, soybeans or peanuts, or any of the ingredients. It must not be used in people who have porphyria (an inability to break down chemicals called porphyrins) or people who have certain skin diseases caused by exposure to light. For the full list of restrictions, see the package leaflet.

Why is Ameluz authorised in the EU?

The European Medicines Agency concluded that the benefits of treatment with Ameluz were greater than the few and mostly mild side effects, and that Ameluz was more effective and somewhat safer than the standard alternative. The Agency therefore concluded that the benefits of Ameluz are greater than its risks and it can be authorised.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Ameluz have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Ameluz are continuously monitored. Side effects reported with Ameluz are carefully evaluated and any necessary action taken to protect patients.

Other information about Ameluz

Ameluz received a marketing authorisation valid throughout the EU on 14 December 2011.

Further information on Ameluz can be found on the Agency's website: ema.europa.eu/Find/medicine/Human_medicines/European_Public_Assessment_Reports.

This overview was last updated in 03-2018.