HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Metvixia safely and effectively. See full prescribing information for Metvixia.

METVIXIA (methyl aminolevulinate) Cream, 16.8%
For Topical Use Only
Initial U.S. Approval: 2004

----------INDICATIONS AND USAGE----------

Metvixia Cream, a porphyrin precursor, in combination with the Aktilite CL128 lamp, a narrowband, red light illumination source, is indicated for treatment of thin and moderately thick, non-hyperkeratotic, non-pigmented actinic keratoses of the face and scalp in immunocompetent patients when used in conjunction with lesion preparation in the physician's office when other therapies are considered medically less appropriate (1)

---------- DOSAGE AND ADMINISTRATION ----------

Photodynamic therapy with Metvixia Cream is a multi-stage process comprised of:

- lesion preparation
- application of Metvixia Cream
- occlusion for 3 hours
- removal of excess cream with saline
- illumination with the Aktilite CL128 lamp emitting a narrow output spectrum red light with a peak at 630 nm and a spectral half-width of approximately 20 nm at a light dose of 37 J/cm^2 using the Aktilite CL128 lamp.

Two treatment sessions should be administered one week apart. Multiple lesions may be treated during the same treatment session using a total of not more than 1 grams (half tube) of Metvixia Cream. Wear nitrile gloves at all times during this procedure. (2)

Metvixia Cream is not for ophthalmic, oral or intravaginal use. (2)

----------DOSAGE FORMS AND STRENGTHS----------

Metvixia Cream, 16.8% (3)

---------- CONTRAINDICATIONS ----------

Metvixia Cream is contraindicated in patients with (4):

- cutaneous photosensitivity
- known allergies to porphyrins
- known sensitivities to any of the components of Metvixia Cream, which includes peanut and almond oil

----------WARNINGS AND PRECAUTIONS----------

Metvixia Cream is intended for topical use in the physician's office by physicians only . The recurrence rate of treated lesions is unknown. (5.1)

- Patients and providers should wear protective eyewear before operating the Aktilite lamp. Patients should be cautioned with regard to protective clothing after exposure to Metvixia (5.2).
- Do not apply to the eyes or to mucous membranes. Metvixia Cream has demonstrated a high rate of contact sensitization (allergenicity) (5.3) .

----------ADVERSE REACTIONS ----------

Most common related adverse reactions (incidence greater than 10% and greater than placebo) are erythema; pain, burning and discomfort; pruritus; scabbing, crusting and erosions; edema and exfoliation of the skin (6)

To report SUSPECTED ADVERSE REACTIONS, contact XXXX at 1-8XX-XXXX or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------USE IN SPECIFIC POPULATIONS ----------

No overall differences in safety and efficacy were observed between patients aged 65 years and older and those who were younger (8.5)

See 17 for PATIENT COUNSELING INFORMATION and FDA approved labeling

Revised: 6/2008

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Metvixia Cream in combination with Aktilite CL128 lamp red light illumination is indicated for treatment of thin and moderately thick, non-hyperkeratotic, non-pigmented actinic keratoses of the face and scalp in immunocompetent patients. This photodynamic therapy should be used in conjunction with appropriate lesion preparation in the physician's office when other therapies are considered medically less appropriate [*See Dosage and Administration (2)*].

The safety and efficacy have not been established for the treatment of cutaneous malignancies or for skin lesions other than non-hyperkeratotic face and scalp actinic keratoses using PDT with Metvixia Cream. The safety and efficacy of Metvixia Cream have not been established in patients with immunosuppression, porphyria or pigmented actinic keratoses.

2 DOSAGE AND ADMINISTRATION

Photodynamic therapy (PDT) for non-hyperkeratotic actinic keratoses with Metvixia Cream is a multi-stage process as described below: Two treatment sessions one week apart should be administered. Not more than one gram (half tube) of Metvixia Cream should be applied per treatment session. Multiple lesions may be treated during the same treatment session using a total of one gram of Metvixia Cream. Lesion response should be assessed 3 months after the last treatment session. Nitrile gloves should be worn when applying and removing the cream.

The Aktilite CL128 lamp, which is equipped with light emitting diodes (LEDs), emits red light with a narrow spectrum at approximately 630 nm, and a half-width of approximately 20 nm. The light dose to be used is 37 J/cm^2, and the lamp should be placed 50 to 80 mm from the skin. The area of skin that can be illuminated is 80 x 180 mm. Calibration by the operator is not needed, and the illumination time is calculated automatically. The LED panel window should be cleaned daily with a slightly moist clean cloth.

If Aktilite red light treatment is interrupted or stopped for any reason, it may be restarted. If the patient for any reason cannot have the red light treatment during the prescribed period after application (the 3 hour timespan), the cream should be rinsed off and the patient should protect the exposed area from sunlight, prolonged or intense light for at least 48 hours.

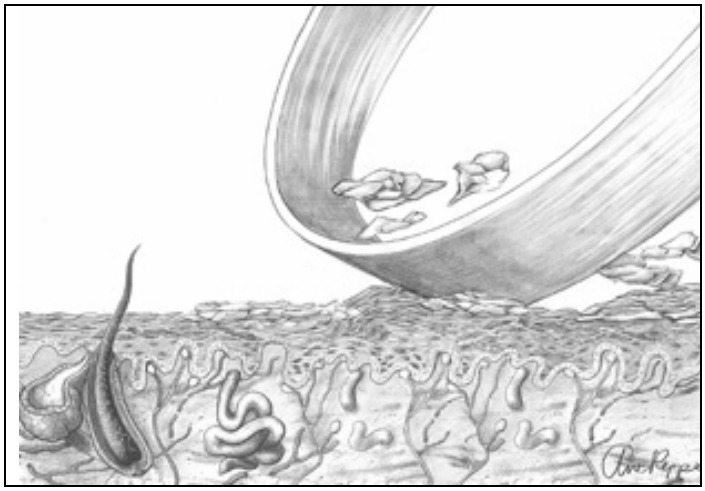
Use of Metvixia Cream without subsequent red light illumination is not recommended.

This product is to be used only by physicians in the physician's office. Metvixia Cream is not for ophthalmic, oral, or intravaginal use. Physicians should be knowledgeable about photodynamic therapy and familiar with the Aktilite Operators Manual prior to use of Metvixia Cream.

One Metvixia-PDT session consists of:

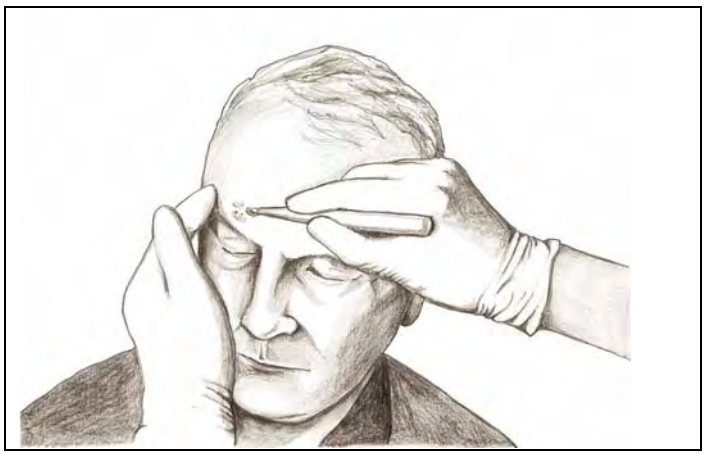
- Lesion preparation *[See Dosage and Administration (2.1)]*

- Application of Metvixia Cream *[See Dosage and Administration (2.2)]*
- Application of occlusive dressing *[See Dosage and Administration (2.3)]*
- Occlusion for 3 hours *[See Dosage and Administration (2.4)]*
- Removal of excess cream with saline *[See Dosage and Administration (2.5)]*
- Positioning Aktilite CL128 lamp *[See Dosage and Administration (2.6)]*
- Illumination with red light (Aktilite CL128 lamp) *[See Dosage and Administration (2.7)]*



2.1 Lesion preparation
Before applying Metvixia Cream, the surface of the lesions should be prepared with a small dermal curette to remove scales and crusts and roughen the surface of the lesion. This is to facilitate access of the cream and light to all parts of the lesion.

Figure 1A Lesion debriding

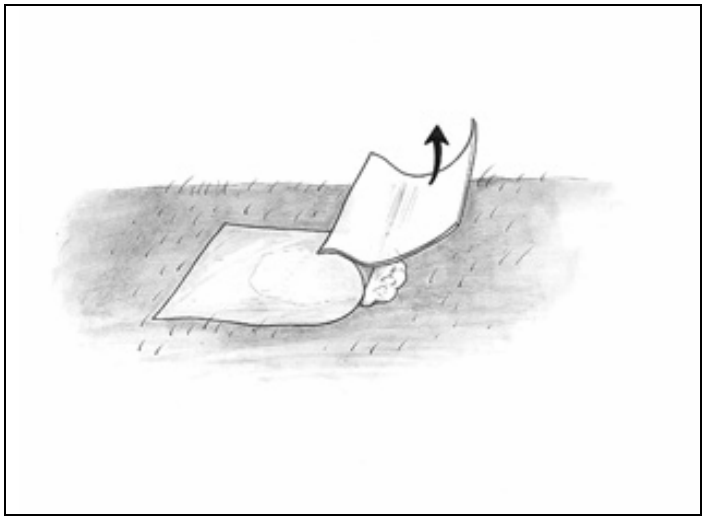


Only nitrile gloves should be worn during this and subsequent steps and Universal Precautions should be taken. Vinyl and latex gloves do not provide adequate protection when using this product.

Figure 1B Lesion debriding

2.2 Application of Metvixia Cream
Using a spatula, apply a layer of Metvixia Cream about 1 mm thick to the lesion and the surrounding 5 mm of normal skin. Do not apply more than one gram (half tube) of Metvixia Cream per treatment session.

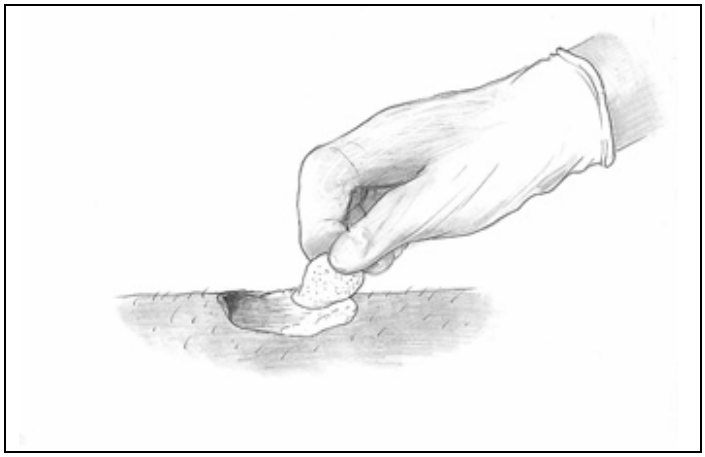
Figure 2: Cream application



2.3 Occlusive Dressing – Cover
The area where the cream has been applied should then be covered with an occlusive, non-absorbent dressing for 3 hours. Multiple lesions may be treated during the same treatment session. Each treatment field is limited to an area of 80 x 180 mm.

Figure 3: Occlusive dressing application

2.4 Occlusion for 3 hours - (at least 2.5 hours, but no more than 4 hours).
After Cream application, patients should avoid exposure of the photosensitive treatment sites to sunlight or bright indoor light (e.g., examination lamps, operating room lamps, tanning beds, or lights at close proximity) during the period prior to Aktilite red light treatment. Exposure to light may result in a stinging and/or burning sensation and may cause erythema and/or edema of the lesions. Patients should protect treated areas from the sun by wearing a wide-brimmed hat or similar head covering of light-opaque material. Sunscreens will not protect against photosensitivity reactions caused by visible light. It has not been determined if perspiration can spread the Metvixia Cream outside the treatment site to the eyes or surrounding skin. The treated site should be protected from extreme cold with adequate clothing or remaining indoors between application of Metvixia Cream and Aktilite PDT light treatment.



2.5 Removal of Excess Cream with Saline
Following removal of the occlusive dressing, clean the area with saline and gauze. Wear nitrile gloves.

Figure 4: Cream removal

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