

17 PATIENT COUNSELING INFORMATION

The physician should provide and discuss the attached Patient Package Insert with each patient.

PATIENT INFORMATION

Metvixia (met vik see a) (methyl aminolevulinate hydrochloride) Cream, 16.8%

Read this Patient Information before you are treated with Metvixia Cream and each time you are treated. There may be new information. This leaflet does not take the place of talking with your doctor about your condition or treatment. Ask your doctor provider about anything you do not understand about Metvixia Cream.

Important note: Metvixia is for use on the skin only. Tell your doctor right away if Metvixia gets in your eyes or mouth.

What is the most important thing I need to know about Metvixia Cream?

- Metvixia Cream with light treatment (Photodynamic therapy or PDT) is only done in medical offices by trained doctors.
 - Metvixia Cream is not applied by patients and should not be applied by doctors who have not been trained in its use.
- Metvixia cream is for use in PDT with the Aktilite CL128 lamp.

What is Metvixia Cream?

Metvixia Cream is a prescription cream used with PDT to treat skin growths on the face and scalp called actinic keratosis (AK). Metvixia Cream is only used for AK skin growths that are thin and not dark colored. AK skin growths are caused partly by too much sun exposure. Metvixia Cream and PDT work together to treat AK skin growths.

Metvixia Cream has not been studied in children for any condition and should not be used in children.

Who should not use Metvixia Cream?

Do not use Metvixia Cream if:

- your skin over reacts to sun or light (photosensitivity); Talk with your doctor to be sure
- you are allergic to porphyrins or to any of the ingredients in Metvixia Cream including peanut and almond oil. See the end of this leaflet for a complete list of ingredients in Metvixia Cream.

What should I tell my doctor before treatment with Metvixia Cream?

Tell your doctor about all your medical conditions, including if you

- have or had skin cancer or other skin growths on your body
- have bleeding problems.
- **are pregnant or planning to become pregnant.** It is not known if Metvixia Cream can harm your unborn baby.
- **are breastfeeding.** It is not known if Metvixia Cream passes into your milk and if it can harm your baby. You should decide whether or not to stop breastfeeding while getting treatment with Metvixia Cream. Talk to your doctor for help with this choice.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. It is not known if Metvixia Cream and other medicines can affect each other.

Know your medicines. Keep a list of your medicines and show it to your doctor and pharmacist when you start a new medicine.

How should I use Metvixia Cream?

- Metvixia Cream and PDT treatment is only done by trained doctors.
- You will receive 2 treatments with Metvixia Cream and PDT 1 week apart. Your doctor will check you three months after treatment to see if the treatment worked for you. (See the end of this leaflet for the section “Treatment with Metvixia Cream and PDT.”)

Metvixia Cream is for skin use only. Do not get Metvixia Cream in your eyes or mouth. Tell your doctor right away if this happens.

What should I avoid while using Metvixia Cream?

- **During the 3 hours that Metvixia Cream is on your skin:**
 - Avoid sunlight or bright indoor light (for example: examination lights, operating room lights, tanning beds or lights that are close to you). During this time, the treated areas of your skin are more sensitive to light. You may feel burning or stinging. Your treated skin may become red or your lesions may become swollen. Wear a protective hat and clothing if you need to be outside in the sun.
 - Avoid cold temperatures. Wear warm clothing and keep your treated skin areas covered if you are in cold temperatures, or stay indoors.
- **After treatment with Metvixia cream and PDT**, avoid sunlight or bright indoor light (for example: examination lights, operating room lights, tanning beds or lights that are close to you) for two days. During this time, the treated areas of your skin are more sensitive to light. Keep the treated areas of your skin covered. Wear a protective hat and clothing if you need to be outside in the sun.

- **If for any reason you are not treated with the lamp after Metvixia Cream has been applied to your skin:**
 - Carefully rinse off the Cream.
 - Avoid sunlight, indoor light that is bright (for example: examination lights, operating room lights, tanning beds or lights that are close to you) for two days after treatment. During this time, the treated areas of your skin are more sensitive to light. Wear a protective hat and clothing if you need to be outside in the sun.

What are the possible side effects of Metvixia Cream with PDT treatment?

Common side effects of Metvixia Cream with PDT treatment include the following skin reactions at the treated site:

- redness
- pain
- burning feeling
- stinging
- swelling
- crusting, peeling, blisters, bleeding, itching ulcers

Burning pain and stinging usually decline over a few hours. If skin redness, swelling and other signs of inflammation get worse and last longer than 3 weeks, call your doctor.

Tell your doctor about any side effects that bother you or do not go away. Your doctor should be able to treat them if needed.

These are not all the side effects of Metvixia Cream with PDT. Ask your doctor or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about Metvixia Cream

This leaflet summarizes the most important information about Metvixia Cream. If you would like more information, talk with your doctor. You can ask your doctor for information about Metvixia Cream that is written for health professionals.

Toll-free number and/or website will be provided when available for the US market.

What are the ingredients in Metvixia Cream?

Active Ingredient: methyl aminolevulinate hydrochloride

Inactive Ingredients: Glyceryl monostearate, cetostearyl alcohol, poloxyl stearate, cholesterol, oleyl alcohol glycerin, white petrolatum, isopropyl myristate, refined peanut oil, refined almond oil, edetate disodium, methylparaben and propylparaben.

Treatment with Metvixia Cream and PDT

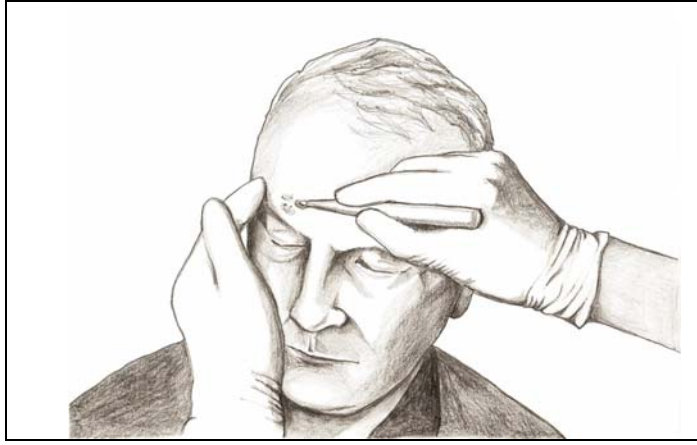


Figure 1: Lesion debridement

Your doctor will prepare your skin by gently scraping (debriding) your skin growths before treating with Metvixia Cream and PDT. A small skin scraper is used to remove scales and crusts and to roughen the surface of any skin growths. This is to help Metvixia Cream and PDT to reach all parts of the skin growths.



Figure 2: Cream application

Metvixia Cream is applied to the actinic keratosis skin growths and to a small area of the skin around the growths.

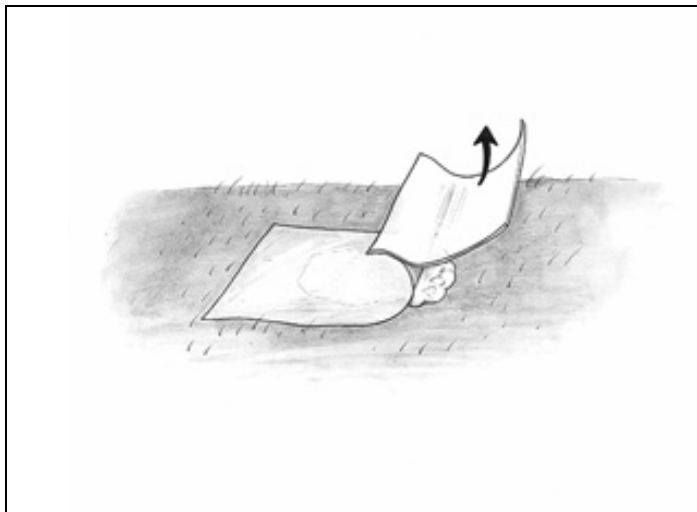


Figure 3: Clear bandage application

The treated skin areas will be covered with a special clear bandage for about 3 hours.

During these 3-hours avoid sunlight or bright indoor light (for example: examination lights, operating room lights, tanning beds or lights that are close to you). During this time, the treated areas of your skin are more sensitive to light. You may feel burning or stinging. Your treated skin area may turn red or become swollen (photosensitive reactions). Wear a hat and protective clothes if you need to be out in the sun during this time. Sunscreens will not help protect your treated skin during this time. In cold weather, protect your treated skin site from the cold with warm clothes or stay indoors for these 3 hours between the cream and light treatment.

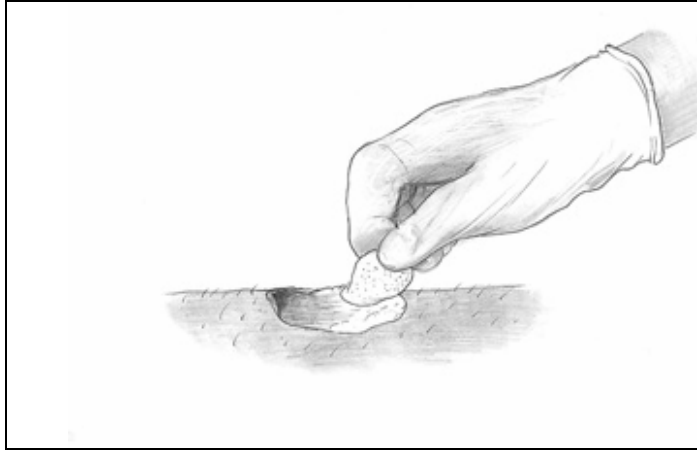


Figure 4: Cream removal

The bandage will be removed and the area will be rinsed with a saline solution before the PDT (light) treatment.

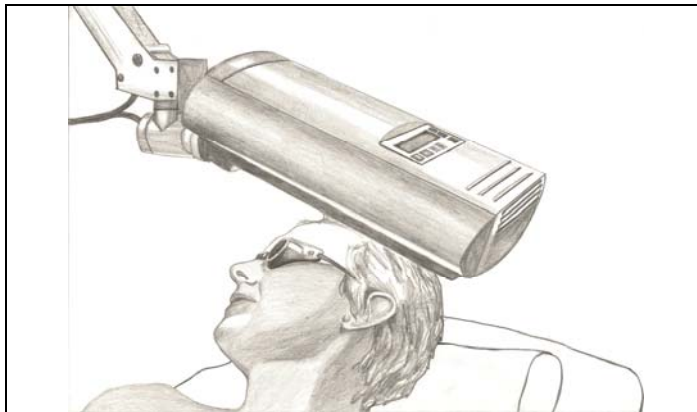


Figure 5: Positioning the lamp

The lamp will be positioned over the area to be illuminated by the use of guide light of reduced intensity. The distance between the lamp and the skin will be 50 to 80 mm (2-3.2 inch).

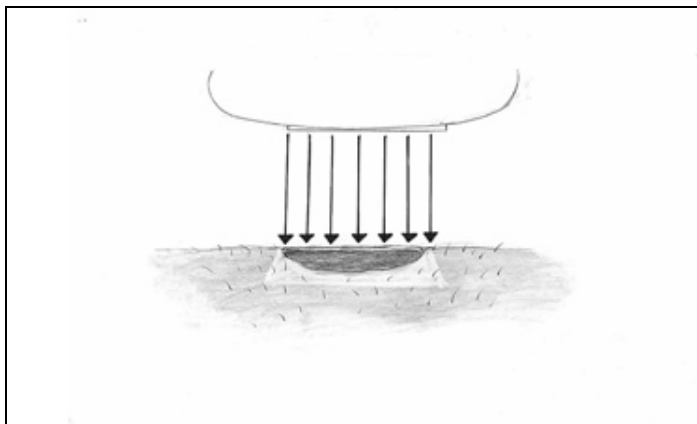


Figure 6: Illumination

The skin growth will be treated with PDT. PDT lasts about 10 minutes for each area treated with the lamp. You and your doctor will wear goggles to cover and protect your eyes from the light during this part of the treatment. Do not stare into the beam.

More than 1 skin growth may be treated at a time. Your treated skin areas may burn, feel painful, sting, or tingle during light treatment. The Aktelite light treatment can be stopped for a short period of time (paused) and then restarted if needed. Tell your doctor to stop the

light if you need the treatment paused because of discomfort, or if you need to adjust your goggles. If you cannot have the light treatment 3 hours after Metvixia Cream is applied, rinse the cream off your skin, protect your skin from sunlight and bright indoor light (for example: examination lights, operating room lights, tanning beds or lights that are close to you) for two days.

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Metvixia Cream is a trade name of PhotocureASA.

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