Metvix® Cream

Methyl aminolevulinate 160mg/g

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about METVIX. It does not contain all the available information.

It does not take the place of talking to your doctor or nurse.

All medicines have risks and benefits. Your doctor has weighed the risks of you using METVIX against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or nurse.

Keep this leaflet. You may need to read it again.

What METVIX is used for

METVIX contains the active ingredient methyl aminolevulinate (as hydrochloride) that belongs to a group of medicines called antineoplastic agents or cytotoxic medicines. You may also hear of these being called chemotherapy medicines.

METVIX is used for treating spots on the face and scalp that are thin and not dark-coloured, that are at risk of turning into skin cancer (pre-cancerous lesions called actinic keratosis, or AK). It is used when other treatments are considered unacceptable. METVIX is also used to treat some shallow basal cell carcinomas (BCCs) (a form of skin cancer) as well as Bowen's disease, when surgery is not a suitable option. Bowen's disease is a persistent, flat, red-brown scaly or crusted area on the skin which is due to a tumour inside the upper layer of the skin. If untreated it may spread or eventually invade deeper structures of the skin.

METVIX works by killing cancer or pre-cancer cells by preventing them from growing or multiplying. Treatment consists of application of Metvix cream followed by light exposure (Photodynamic Therapy or PDT) using either a red LED lamp (for AK, BCCs and Bowen's disease) or daylight (for AK only). The affected areas absorb methyl aminolevulinate from the cream. By light exposure, the cancerous cells are destroyed. Normal skin will not be affected.

Ask your doctor if you have any questions about why METVIX has been prescribed for you.

Your doctor may have prescribed it for another reason.

METVIX is not addictive.

METVIX is available only with a doctor's prescription.

Before you use METVIX

When you must not use it

Do not use METVIX:

- For children under 18 years of age
- If you have porphyria (a rare blood pigment disorder)
- If you have a type of Basal Cell Carcinoma (BCC) called morpheaform.
- If you have a type of skin cancer called invasive squamous cell carcinoma
- If you have an allergy to any medicine containing methyl aminolevulinate
- If you have an allergy to arachis (peanut) oil
- If you have an allergy to any of the ingredients listed at the end of this leaflet

Symptoms of an allergic reaction, which can lead to angioedema, may include:

- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives of the skin, especially on the areas of the skin where the cream was applied.

Tell immediately your Doctor if you have a history of allergies; they may give you a small test dose to see how you react to METVIX.

Do not use METVIX after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.
If it has expired or is damaged, return it to your doctor or nurse for disposal.

Before you start to use it

METVIX should only be used on thin and non-pigmented actinic keratosis (pre-cancerous lesions or AK). The performance of Metvix on thicker, deeper or darker skin cancers is unknown.

METVIX should only be used on the first presentation of any Basal Cell Carcinomas (BCCs). The performance of METVIX on recurring BCCs is unknown.

METVIX should only be used on non-pigmented, small (<40 mm diameter) and non- genital Bowen's disease lesions. The performance of Metvix on larger, deeper, darker or genital skin cancers is unknown.

Before you start treatment with METVIX**,** any UV-treatment on your skin should be ceased.

METVIX treatment with red LED lamp should only be administered in the presence of a doctor, a nurse, or other health care professional trained to apply Photodynamic Therapy (PDT).

Tell your doctor if you are pregnant or plan to become pregnant.
Like most antineoplastic medicines, METVIX is not recommended for use during pregnancy. It is unknown whether METVIX may affect your developing baby if you use it during pregnancy. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breast-feeding.
A risk to the new-borns/infants cannot be excluded. To avoid the possibility that the baby may be affected by METVIX, you should cease breast-feeding while using METVIX and for 2 days after treatment.

Tell your doctor if you have a history of high blood pressure. Your doctor may decide to measure your blood pressure if you experience severe pain during illumination with the red LED lamp. If your blood pressure is high, your doctor may then decide to stop the procedure.

If you have not told your doctor about any of the above, tell him/her before treatment with METVIX.

Taking other medicines

Tell your Doctor or Nurse if you are using any other medicines, creams or ointments, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and METVIX may interfere with each other. Your Doctor and Nurse may have more information on medicines to be careful with while using METVIX.

How to use METVIX

Health care professionals will perform all of the steps in your treatment:

The treatment session begins with preparation of the cancerous or pre-cancerous skin by removing scales and crusts and roughening of the skin surface. Some Basal Cell Carcinomas (BCCs) are often covered by an intact layer of skin which should be removed. This helps METVIX cream and light treatment to reach affected skin.

METVIX cream is then applied by spatula in a layer to the lesion and a small area of the surrounding skin.

Avoid getting the METVIX cream into your eyes. METVIX cream should not be applied to eyelids and mucous membranes.

PDT with a red LED lamp

If your Doctor prescribes photodynamic therapy (PDT) treatment with a red LED lamp source with your Metvix, your lesions are prepared as described above. After Metvix cream is applied, the area will be covered with a dressing, and this should remain in place for 3 hours. The dressing and the cream are then gently removed with saline water, and finally the treated area will immediately be exposed to PDT via a red LED lamp source. Eyes should be protected from intense LED light, so you will be given goggles to wear during this

treatment.

As a general precaution, sun exposure of the treated area and surrounding skin should be avoided for about 2 days following treatment**.**

Daylight PDT

Your Doctor will only prescribe daylight PDT if you have actinic keratosis on the face and scalp, and the weather is suitable to stay comfortably outdoors for 2 hours. If the weather is rainy, or is likely to become so, Metvix daylight treatment should not be used. An appropriate sunscreen should be applied to all exposed areas. The sunscreen used must offer adequate protection (Sun Protection Factor (SPF) 30 or higher). Only sunscreens with chemical filters should be used with daylight PDT. The sunscreens should not include physical filters (such as titanium dioxide, zinc oxide or iron oxide) as these filters interrupt the effectiveness of the daylight PDT treatment.

If your Doctor prescribes daylight PDT treatment, your lesions are prepared as described above 15 minutes after sunscreen application. After Metvix cream is applied, no occlusion is necessary before daylight exposure. Treatment with daylight should begin within 30 minutes of Metvix cream application, and should continue for 2 hours. During this time, you should remain outside and carry out usual daily activities. On sunny days, if you feel uncomfortable in direct sunlight, you may take shelter in the shade. Following the 2 hours exposure period, the cream will be removed with saline water. As a general precaution, sun exposure of the treated area and surrounding skin should be avoided for about 2 days following treatment**.**

Follow up treatment sessions

Only 1 treatment session of PDT (either with red LED light or daylight) is required for AK. Multiple skin lesions may be treated during the same treatment session. Your Doctor will assess the response after 3 months. Treatment may be repeated once only after this period, if necessary. This repeat treatment will also be a single session.

Treatment for BCC and Bowen's disease will consist of 2 sessions of PDT with red LED light, 1 week apart. Multiple skin lesions may be treated during the same treatment session. Your doctor will assess the response after three months. Treatment may be repeated once only after this period, if necessary. This repeat treatment will also consist of two sessions, one week apart. The sites of successfully treated lesions should be reviewed at 6-12 monthly intervals to detect recurrence.

Tell your Doctor if you notice that any of the areas of skin treated with Metvix have changed or appear worse

What if I am given too much METVIX

If the application time or the light dose is increased, a more severe local reaction might result. You should contact your doctor or nurse if you have any concerns.

What if treatment is stopped

If the treatment is stopped before the full light dose has been given with the red LED light, or before the end of the 2 hour daylight exposure, the success of the treatment might be compromised.

Whilst you are using METVIX

Things you must do

Tell all doctors and nurses who are treating you that you are using METVIX.

If you feel that METVIX is not helping your condition, tell your doctor or nurse.

Tell your doctor if you become pregnant while using METVIX.

Things you must not do

After undergoing METVIX treatment, ensure the treated area and surrounding skin are protected from sunshine for 2

days after treatment.

Side effects

Tell your doctor or nurse as soon possible if you do not feel well whilst you are using METVIX.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or nurse to answer any questions you may have.

Tell your Doctor or Nurse if you notice any of the following and they worry you:

- Local discomfort at the treatment site during and after light exposure including skin burning, warm sensation, pricking and tingling skin or stinging sensation, swelling, pain, itching of skin and redness
- Crusting, ulceration, weeping or discharge, blistering, peeling, bleeding skin, skin infection and changes to the colour of the skin
- Headache

These are more common side effects of METVIX, particularly with red LED light Photo Dynamic Therapy (PDT).

The most frequent of these symptoms is a painful and burning skin sensation, typically beginning during or soon after red light exposure, lasting for a few minutes to hours and resolving on the day of treatment. Severity of these symptoms is usually mild or moderate, but rarely, it may require early termination of illumination.

Treatment with daylight PDT is associated with similar type of side effects but significantly less pain, and substantially less local discomfort than with red LED light PDT.

Tell your Doctor or nurse if you notice any of the following:

- nettle rash (urticaria)
- skin rash
- allergic reaction which can lead to angioedema with the following symptoms: swelling of the face, the tongue or the throat, or difficulty in breathing
- eczema or thinning of skin
- dizziness
- Memory loss or confusion state or disorientation
- eye pain and eye irritation
- swollen eyes, eyelids, face
- nausea
- fatigue
- skin irritation
- wound haemorrhage

Increase of blood pressure may be induced by pain associated with the use of red light.

These are uncommon side effects of METVIX or their frequency is unknown.

Other side effects not listed above may occur in some patients. Do tell your Doctor or Nurse if you notice any side effects not mentioned in this leaflet.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using METVIX

Storage

METVIX should be stored in a refrigerator, below 8ºC. An opened tube should be used within 3 months.

Keep out of the reach and sight of children.

Product description

What it looks like

METVIX contains 160 mg/g of methyl aminolevulinate (as hydrochloride) and is cream to pale brown in colour.
It is supplied in a tube containing 2 g cream.

Ingredients

Each gram of METVIX contains 160mg of methyl aminolevulinate as the active ingredient.

It also contains the inactive ingredients:

- glyceryl monostearate

(self-emulsifying)
- cetostearyl alcohol
- PEG-40 stearate
- methyl hydroxybenzoate (E 218)
- propyl hydroxybenzoate (E 216)
- disodium edetate
- glycerol
- white soft paraffin
- cholesterol
- isopropyl myristate
- arachis oil (peanut oil)
- almond oil (refined)
- oleyl alcohol
- purified water

Sponsor / distributor

Galderma Australia Pty Ltd
Level 1, 1 Denison Street
North Sydney NSW 2060
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