PACKAGE LEAFLET

Package leaflet: Information for the user

Metvix 160 mg/g cream
Methyl aminolevulinate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Metvix is and what it is used for

Metvix 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. Having these lesions means that you may be more likely to get skin cancer in the future unless they are treated.

Metvix is also used in the treatment of basal cell carcinoma (BBC), a skin cancer that can cause a reddish, scaly patch (called superficial BBC) or a small bump or a series of small bumps on the skin (called nodular BCC). These lesions bleed easily and do not heal. Metvix is used when other therapies are not suitable.

Metvix can also be used to treat Bowen's disease (a pre-cancerous lesion appearing as slowly enlarging reddish-pink patches) when surgery is not suitable.

The treatment consists of application of Metvix and light exposure. Damaged skin cells absorb methyl aminolevulinate from the cream and are destroyed by light exposure (known as photodynamic therapy). The surrounding healthy skin is not affected.

2. What you need to know before you use Metvix

Do not use Metvix
- if you are allergic to methyl aminolevulinate or any of the other ingredients of this medicine (listed in section 6). Metvix contains arachis oil (peanut oil): Do not use this product if you are allergic to peanut or soya
- if you have a particular type of skin cancer with yellowish-white patches called morpheaform basal cell carcinoma
- if you have a rare disease called porphyria.

Warnings and precautions
Talk to your doctor before using Metvix:
- if the skin lesions are of certain types (coloured, deep or located on the genitalia)

- if you have ‘thick’ actinic keratoses
- if you have large lesions caused by Bowen’s disease
- if you are taking medicines to suppress your immune system such as steroids or ciclosporin
- if your Bowen’s disease has been caused by exposure to arsenic (a harmful chemical)
- if you have a history of high blood pressure

Direct eye contact with Metvix should be avoided. Metvix cream should not be applied to the eyelids and mucous membranes.
The active substance may cause skin allergy which can lead to angioedema. If you experience the following symptoms: swelling of the face, the tongue or the throat; rash, or difficulty in breathing, you should immediately stop taking Metvix and contact a doctor.
If using a red-light source and the application time or the light dose is increased, a more severe skin reaction may result (see Section 4 – Possible side effects).
In very rare cases photodynamic therapy with a red light source may increase the risk to develop temporary memory loss (including confusion or disorientation), in case of symptoms, you should contact your doctor immediately.

Sun exposure and UV therapy
As a general precaution, sun exposure on the treated lesion sites and surrounding skin should be avoided for a couple of days following treatment. If you are being treated with ultraviolet light (UV-therapy), this treatment should be stopped before Metvix treatment.

Pregnancy and breast-feeding
Treatment with Metvix is not recommended during pregnancy.
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines
No effects on the ability to drive and use machines are expected.

Metvix contains arachis oil (peanut oil), cetostearyl alcohol and methyl- and propyl parahydroxybenzoate.
If you are allergic to peanut or soya (containing arachis oil), do not use this medicinal product.
Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).
Methyl- and propyl parahydroxybenzoate (E218, E216) may cause allergic reactions (possibly delayed).

3. How to use Metvix

The treatment consists of application of Metvix and light exposure. The illumination source for treatment of actinic keratoses can be daylight (natural or artificial) or a red-light lamp. Your doctor will decide which treatment option to use, depending on your lesions. The illumination source for treatment of basal cell carcinoma and Bowen’s disease is always a red-light lamp.

Adults (including the older people)

Treatment of actinic keratoses, basal cell carcinoma and Bowen’s disease using a red-light lamp

The use of Metvix with a red-light lamp requires specific knowledge in photodynamic therapy. Accordingly, it should be administered in the presence of a doctor, a nurse or another health care professional trained in the use of photodynamic therapy.

Preparation of the lesions and application of the cream
Each skin lesion will be prepared before treatment, by removing scales and crusts and roughening of the skin surface. This preparation helps Metvix and light to get to all parts of the skin lesion. Some skin cancer lesions are covered by an intact layer of skin which will be removed according to your doctor's instructions.

Metvix is applied by a spatula in a layer (about 1 mm thick) to the lesions or fields and a small area of the surrounding skin. Direct eye contact with Metvix cream should be avoided. After the cream is applied, the area is covered with a dressing. The dressing is removed and the cream is washed off with saline solution after 3 hours.

Illumination using a red-light lamp
Immediately after cleaning, the treated area is exposed to a red-light. To protect your eyes from the strong light, you will be given goggles to wear during light exposure.
Several lesions or fields may be treated during the same therapy session.

Treatment of actinic keratoses with natural daylight

Considerations before treatment
Natural daylight treatment can be used if the temperature is suitable to stay comfortably outdoors for 2 hours. The efficacy of the treatment has been shown to be similar whether the treatment is done on a sunny or cloudy day. If the weather is rainy, or is likely to become so, natural daylight treatment should not be used.

Preparation of the lesions and application of the cream
An appropriate sunscreen should be applied to all areas, including the treatment areas that will be exposed to daylight before lesion or field preparation. Only the sunscreen that has been recommended specifically by your doctor should be used. Do not use sunscreen with physical filters such as titanium dioxide, zinc oxide as these filters would inhibit absorption of visible light and may impact efficacy. Only sunscreens with chemical filters should be used.

Each skin lesion will be prepared before treatment, by removing scales and crusts and roughening of the skin surface. This preparation helps Metvix and light to get to all parts of the skin lesion.

A thin layer of Metvix is applied on the lesions or fields with a spatula or gloved hand. Direct eye contact with Metvix cream should be avoided.

Illumination using natural daylight
You should go outside after Metvix application, or at the latest, 30 minutes later and stay for 2 hours in full daylight or, if needed, in a shaded outdoor area. It is recommended not to go indoors during this time period. Make sure the treatment area is continuously exposed to daylight, and not covered by clothes. It is important to follow these instructions to ensure treatment success and avoid pain during daylight exposure. Following the 2-hour exposure period Metvix cream is washed off.
Several lesions or fields may be treated during the same therapy session.

Treatment of actinic keratoses using an artificial daylight lamp

The use of Metvix with an artificial daylight lamp requires specific knowledge in photodynamic therapy. Accordingly, it should be administered in the presence of a doctor, a nurse or another health care professional trained in the use of photodynamic therapy.

Preparation of the lesions and application of the cream
Each skin lesion will be prepared before treatment, by removing scales and crusts and roughening of the skin surface. This preparation helps Metvix and light to get to all parts of the skin lesion. A thin

layer of Metvix is applied on the lesions or fields with a spatula or gloved hand. Direct eye contact with Metvix cream should be avoided.

Illumination using an artificial daylight source
After the cream is applied, or at the latest, 30 minutes later, the treated area is exposed to artificial daylight for 2 hours. Following the 2 hour-exposure period, Metvix cream is washed off.
Several lesions or fields may be treated during the same therapy session.

Number of treatments
- Actinic keratoses are treated with one session.
- Basal cell carcinoma and Bowen's disease is treated with two sessions, with an interval of one week in between sessions.

Follow up
Your doctor will decide how well each skin lesion has responded after three months and may take a small sample (biopsy) of the skin and have the cells examined. Treatment may be repeated after this period if necessary.

Use in children and adolescents
Treatment with Metvix is not suitable for use in children or adolescents below 18 years of age.

If you stop using Metvix
If the treatment is stopped before the light therapy is started or full light dose is given, when using the red light, or before the end of the 2 h daylight exposure the effectiveness of the treatment might be reduced.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects below have been reported when using Metvix with red light. The clinical trial studies where Metvix was used with daylight showed similar types of side effects apart from a significant decrease in pain when using daylight.

Very common (may affect more than 1 in 10 people): skin pain (with red light), skin burning sensation, scab, redness of the skin.

Painful and burning skin sensations at the treatment site during and after light exposure are the most common side effects, occurring in more than half of patients treated. These reactions are usually of mild to moderate severity but rarely require the light therapy to be stopped early. These reactions usually start during light therapy or soon after and last for a few hours, generally improving on the day of treatment. Redness and swelling may persist for 1 to 2 weeks, or occasionally for a longer time period. Repeated treatment does not make these reactions worse.

Common (may affect up to 1 in 10 people):
- Effects at treatment site: numbness, tingling or prickling sensation, bleeding (can occur following lesion preparation), warm skin, infection, open sores (ulceration), swelling / oedema of the skin, blistering, itching, flaking of the skin, weeping.
- Effects away from treatment site: headache, feeling hot.

Uncommon (may affect up to 1 in 100 people):
- Effects at treatment site: skin irritation, hives, rash, areas of paler or darker skin after healing, sensitivity to light, discomfort, eye swelling, eye pain, nausea, heat rash, tiredness.

Not known (frequency cannot be estimated from the available data):

- Allergic reaction which can lead to angioedema with the following symptoms: swelling of the face, the tongue or the throat, or difficulty in breathing.
- Eye lid swelling, pustules and eczema (dry flaky skin) on application site and signs of contact allergy.
- Increase of blood pressure may be induced by pain associated with the use of red light.
- Temporary memory loss (including confusion or disorientation).

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance

Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Metvix

Keep this medicine out of the sight and reach of children.
Store in a refrigerator (2°C – 8°C).
Once opened the cream should be used within 3 months.

Do not use this medicine after the expiry date which is stated on the carton and tube. The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible signs of deterioration (e.g. darkening of the colour from pale yellow to brown).

Do not throw away any medicines via wastewater or household waste. Ask you pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Metvix contains

- The active substance is methyl aminolevulinate 160 mg/g (as hydrochloride).
- The other ingredients are glyceryl monostearate, cetostearyl alcohol, poloxyl 40 stearate, methyl parahydroxy benzoate (E218), propyl parahydroxybenzoate (E216), disodium edetate, glycerol, white soft paraffin, cholesterol, isopropyl myristate, arachis oil (peanut oil), almond oil, oleyl alcohol, purified water.

What Metvix looks like and contents of the pack

The colour of Metvix is cream to pale yellow. The cream is available in tubes containing 1 g or 2 g cream. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Galderma International,
Tour Europlaza,

20 Avenue André Prothin,
La Défense 4, 92927 Paris,
La Défense CEDEX,
France

Manufacturer
Laboratoire GALDERMA
ZI Montdésir
74540 ALBY SUR CHERAN
FRANCE

This medicinal product is authorised in the Member States of the EEA under the following names:
AT, BE, CZ, DE, DK, EL, ES, FI, IE, IS, IT, LU, NL, NO, PT, SE, SK, UK: Metvix

This leaflet was last revised in February 2025