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
2. What you need to know before you use Metvix
3. How to use Metvix
4. Possible side effects
5. How to store Metvix
6. Contents of the pack and other information

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 (BCC), a skin cancer that can cause a reddish, scaly patch (called superficial BCC) 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 that can occur on the genitalia), Bowen’s disease that has been caused by exposure to arsenic (a harmful chemical), or Bowen’s disease caused 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 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.

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 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, you should immediately stop taking Metvix and contact a doctor.

If you have any further questions, ask your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

3. How to use Metvix

The treatment consists of application of Metvix and light exposure. The illuminated 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 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.

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).

4. Possible side effects

- 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 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, you should immediately stop taking Metvix and contact a doctor.

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.

Methyl aminolevulinate
160mg/g Cream
Methyl aminolevulinate

Galdérmia Laboratories
Product code: P66175-10
Product description: METVIX CRE 2
Market: GIR
Article: Leaflet
Flat size: 180x315
Fold size: 180x26,25
Font size: 9 pt

Printing Colors
PMS 432U
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, skin irritation, hives, rash, areas of paler or darker skin, swelling, oedema of the skin, blistering, itching, flaking of the skin, weeping.

Uncommon (may affect up to 1 in 100 people):
- Effects at treatment site: swelling of the face, the tongue or the throat, or difficulty in breathing.
- Eye lid swelling, purpura and eczema (dry flaky skin) on application site and signs of contact allergy.

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.
- Increase of blood pressure may be induced by pain associated with the use of red light.
- Temporary memory loss (including confusion or disorientation).

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.

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 glycerol monostearate, cetearyl alcohol, propyl 40 stearate, methyl parahydroxybenzoate (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 contains 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.

All not pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

UK: Marketing Authorisation Holder
Galderma (U.K.) Limited,
Evergreen House North,
Grafton Place, London,
England, NW1 2DX

IE: Marketing Authorisation Holder
Galderma International,
Tour Europaliza,
20, Avenue André Prothin,
La Défense 4, 92927 Paris, La Défense, CEDEX, France

Marketing Authorisation Numbers
PL 105/0010/068 (UK)
PA 22740/0101 (IE)

Manufacturer
Laboratoire GALDERMA
2 Montsouris
75440 ALIBY SUR CHERAN
FRANCE

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

This leaflet was last revised in August 2022.