

PACKAGE LEAFLET: INFORMATION FOR THE USER

Metvix 160 mg/g cream
Methyl aminolevulinate (as hydrochloride)

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What Metvix is and what it is used for
2. Before you use Metvix
3. How to use Metvix
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1. WHAT METVIX IS AND WHAT IT IS USED FOR

Metvix cream is used in the treatment of pre-cancerous skin lesions on the face and scalp, (known as thin or non-hyperkeratotic and non-pigmented actinic keratoses) when other treatments are considered less appropriate. It is also used in the treatment of certain types of skin cancer: superficial and/or nodular basal cell carcinoma when other available therapies are not suitable due to treatment complications and poor cosmetic results; such as skin lesions on the mid-face or ears, lesions on severely damaged skin, large lesions or recurrent lesions; and intraepithelial squamous cell carcinoma (Bowen's disease) when surgical excision is considered less appropriate.

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

Treatment with Metvix is not suitable for use in children or adolescents less than 18 years of age.

2. BEFORE METVIX TREATMENT

Metvix should only be administered in the presence of a physician, a nurse or other health care professionals trained in the use of Metvix with photodynamic therapy (light therapy).

Do not use Metvix

- if you are hypersensitive (allergic) to methyl aminolevulinate or any of the other ingredients of Metvix. Metvix cream 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 (called morpheaform basal cell carcinoma)
- if you have porphyria (a disorder of porphyrine metabolism).

Take special care with Metvix

- if the skin lesions are of certain types (pigmented or highly infiltrating or located on the genitalia) since there is no experience in treatment thereof with Metvix.
- if you are being treated with UV-therapy, this will be stopped before Metvix treatment starts
- thick actinic keratoses should not be treated with Metvix
- avoid getting Metvix into your eyes.
- if the application time or the light dose is increased, a more severe local skin reaction may result.

Treatment in Bowen's disease is more efficient for small than for large lesions. There is no experience of treating Bowen's disease in patients treated with immunosuppressive therapy or with a history of arsenic exposure.

As a general precaution, sun exposure on the treated lesion sites and surrounding skin should be avoided for a couple of days following treatment.

Pregnancy and breast feeding

Treatment with Metvix is not recommended during pregnancy. Nursing should be discontinued during Metvix treatment and for the next 48 hours after the treatment.

Ask your doctor for advice before taking any medicine.

Driving and using machines

No effects on the ability to drive and use machines are known.

Important information about some of the ingredients of Metvix

The active substance may cause skin allergy. The inactive ingredient cetostearyl alcohol may cause local skin reactions (inflammation). Methyl- and propyl parabenzoate (E218, E216) may cause allergic reactions.

3. HOW TO USE METVIX

Adults (including the elderly)

Each skin lesion will be prepared before treatment, by removing scales and crusts and roughening of the skin surface. This preparation facilitates the access of Metvix and light to all parts of the skin lesion. Skin cancer lesions that are nodular are often 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 lesion and a small area of the surrounding skin. After the cream is applied, the area is covered with a dressing, which remains for 3 hours. The dressing and the cream are then gently removed, and the treated area is immediately exposed to light therapy (photodynamic therapy).

To protect your eyes from the intense light, you will be given goggles to wear during light exposure.

For treatment of pre-cancerous skin lesions (actinic keratoses) one session of photodynamic therapy should be applied. For treatment of basal cell carcinoma and Bowen's disease two sessions should be applied with an interval of one week in between sessions. Multiple skin lesions may be treated during the same treatment session. Your doctor will perform assessment of each skin lesion response after three months. Treatment may be repeated after this period if necessary. To confirm the efficacy in lesions of BCC and Bowen's disease, the doctor may take a small biopsy of the skin and have the cells examined.

Children and adolescents

There is no experience in treatment of children and 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, the effectiveness of the treatment might be reduced.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Metvix can have side effects.

Painful and burning skin sensations at the treatment site during and after light exposure are the most common side effects, occurring in about 60 % of the patients in clinical trials. These local reactions are generally of mild or moderate intensity, but rarely it may require early termination of illumination. Typically, it begins at the time of illumination or soon after and lasts for a few hours, generally resolving on the day of treatment. Redness and swelling may persist for 1 to 2 weeks, or occasionally for longer. Repeated treatment did not increase the frequency or intensity of the local reactions.

Very common (more than 1 out of 10 patients): pain of skin, skin burning sensation, scab, redness of the skin.
Common (more than 1 out of 100 patients, but less than 1 out of 10 patients): numbness, tingling or prickling sensation/experience, headache, skin infection, skin ulcer, skin oedema, skin swelling, blister, skin bleeding, itching, flaking of the skin, skin warm, application site discharge, feeling hot.

Uncommon (more than 1 out of 1000 patients, but less than 1 out of 100 patients): eye swelling, eye pain, wound bleeding, nausea, nettle rash (urticaria), rash, skin irritation, photosensitivity reaction, areas of paleness or darkening of the skin, heat rash, skin discomfort, tiredness.

Application site eczema and contact allergy have been described. Most cases were localised to the treatment area and were not severe; rarely redness and swelling have been more extensive.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. HOW TO STORE METVIX

Keep out of the reach and sight of children.

Store at 2°C – 8°C (in a refrigerator).

An opened tube should be used within one week.

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

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

6. FURTHER 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 cream is cream to pale yellow. The cream is available in tubes containing 2 g cream.

Marketing Authorisation Holder

Name and address of national MA-holder to be inserted

Manufacturer

Penn Pharmaceutical Services Ltd.

Tafarnaubach Industrial Estate

Tredegar, Gwent

NP22 3AA

UK

or

Laboratoire GALDERMA

Zone Industrielle Touvières

74540 ALBY SUR CHERAN

FRANCE

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

This leaflet was last approved on 2008-01-16