New Zealand Consumer Medicine Information

METVIX®

Methyl aminolevulinate (as hydrochloride)

What is in this leaflet

This leaflet answers some common questions about METVIX® metered aerosol. It does not contain all available information. Nor does it take the place of talking to your doctor or pharmacist. Keep this information with your metered aerosol (aerosol). You may need to read it again later.

To find out more about METVIX®

You should ask your doctor or pharmacist if you have any questions about your medicine or if you have any trouble before, during or after using METVIX®.

What METVIX® is used for?

METVIX® is an antineoplastic agent. It is available in tubes containing 2 g cream which is cream to pale brown in colour.

METVIX® is used to treat spots on the face and scalp that are thin and not dark coloured that are at risk of turning into skin cancer (actinic keratosis). It is used when other treatments are considered unacceptable. It is also used to treat primary superficial and nodular forms of basal cell carcinoma (BCC) (a form of skin cancer) when surgery is considered inappropriate. Also it can be used to treat Bowen's disease when surgery is considered inappropriate. Bowen's disease is a persistent, progressive 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. Treatment consists of application of METVIX® cream followed by light exposure (Photodynamic Therapy). The lesions absorb methyl aminolevulinate from the cream. By light exposure, the lesion cells are destroyed. Normal skin will not be affected.

Before you use METVIX®

When not to use METVIX®

You should not use METVIX®:

- if you are hypersensitive (allergic) to methyl aminolevulinate or any of the other ingredients of METVIX® including arachis (peanut) oil.
- if you have porphyria (a disorder of porphyrin metabolism)
- if you have a type of BCC which your doctor will know as morpheaform
- if your doctor has found you have an invasive squamous cell carcinoma of the skin

Before you start to use METVIX®

Take special care with METVIX®:

- if the actinic keratoses lesions are of certain types (dark in colour, or spreading), the lesions may not be treated.

- thick actinic keratoses should not be treated with METVIX®
- avoid getting METVIX® into your eyes.

METVIX® should only be given by a doctor, nurse or other health professional trained to use light treatment.

Protect the treated area from sunshine for a couple of days after treatment.

Use in Pregnancy

Treatment with METVIX® is not recommended during pregnancy.

Breast-feeding

Breast feeding should be stopped during METVIX® treatment and for two days after treatment.

Children

METVIX® treatment is not intended for use in children or adolescents less than 18 years of age.

Use in Elderly

No dosage adjustment is required.

Use in patients with renal or liver impairment

No information is available on the use of METVIX® in this group of patients.

Using METVIX®

How to use METVIX®

Health professionals will perform all of the steps in your treatment.

Actinic keratosis, Bowen's Disease and superficial BCC lesions will be prepared before treatment by removing scales and crusts and roughening of the skin surface. Nodular BCC lesions 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 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.

Treatment for AK will consist of one session. 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 be a single session.

Treatment for BCC and Bowen's Disease will consist of two sessions, one 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.

What will happen if I stop using METVIX®?

If the treatment is stopped before the full light dose has been given, the effectiveness of the treatment might be reduced.

Overdose

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

While you are using METVIX®

Things you must do

Tell your doctor if:

- you think your symptoms have worsened or changed
- you think you are allergic to any of the ingredients contained in METVIX®
- you are or may become pregnant or if you are breastfeeding.

Effects on Ability to Drive or Operate Machinery

METVIX® treatment does not affect your ability to drive or use machines.

Side effects

Local discomfort at the treatment site during and after light exposure is the most common side effect, occurring in between 60 and 80% of the patients in clinical trials:

Very common (more than 1 out of 10 patients): Burning, warm, pricking, tingling skin or stinging sensation, swelling, pain, itching and redness.

Common (more than 1 out of 100 patients, but less than 1 out of 10 patients): Crusting, ulceration, weeping or discharge, blistering, appearance of wound, skin infection, peeling, bleeding skin and changes to the colour of the skin.

Uncommon (more than 1 out of 1000 patients, but less than 1 out of 100 patients): Nettle rash (urticaria) or eczema

These local reactions are generally of mild or moderate intensity, and usually pass, however, swelling may persist for up to one week, and redness for up to two weeks. In some cases, redness has persisted for several weeks and in a few cases it has persisted for more than a year.

There have been isolated reports of anxiety, headache, dizziness, migraine, thinning of the skin, abnormal production of tears, feeling sick, tiredness and influenza-like symptoms. However, it is uncertain whether these events are related to treatment.

If you notice any side effects not mentioned in this leaflet, please inform your doctor.

After using METVIX®

Storage

METVIX® will be stored in a refrigerator, below 8°C.
Keep out of the reach and sight of children.
An opened tube should be used within one week.
Do not use after the expiry date stated on the carton and tube. Do not use if packaging is damaged or shows signs of tampering.

Disposal

If you have been told by your doctor that you will not be needing METVIX® anymore, the unused medicine should be returned to your pharmacist so that it can be disposed of safely.

Product Description

Ingredients

The name of your medicine is METVIX®. The active substance is methyl aminolevulinate (as hydrochloride).

The other ingredients are 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.

Pack size.

METVIX® is supplied in a tube containing 2 g cream.

Manufacturer

METVIX® is manufactured in the United Kingdom and distributed in New Zealand by:
Healthcare Logistics
Auckland

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