The Skin Doctor Ivanhoe
1/1065 Heidelberg Road
Ivanhoe VIC 3079
Phone: (03) 8373 4646
Fax: (03) 8373 4644
theskindoctor.melbourne

PDT Under LED Protocol

How your appointment will look:

Upon arrival at the clinic the Skin Therapist will bring you through to the treatment room to begin your consent process

Your treating Doctor will meet you here to;
1) Finalize your consent
2) Confirm your treatment areas
3) Go through any questions you may have
4) Perform nerve blocks if necessary

The treating doctor will then pass on the remainder of your treatment to the Skin Therapist / Practice Nurse

The Skin Therapist will cleanse the area, perform laser ablation* and apply the treatment

After your incubation period the Practice Nurse will conduct the Light Therapy component of your treatment and go through your aftercare with you

Background:

PDT is a procedure used to treat pre cancerous sun damage spots and superficial type skin cancers. This is used as an alternative to efudix which is usually used for 4-6 weeks and will have far greater side effects and discomfort.

This type of treatment is very useful for people who have multiple pre cancerous sun damage spots on the skin called actinic keratosis. These sun damage spots have a 10 percent chance of becoming skin cancer. This is why it is very important to treat this or at the very least monitor closely. If a sun damage spot becomes a skin cancer they will usually turn into a SCC or squamous cell carcinoma. If these are left untreated they can become invasive and life threatening.

Preparation:

Before undertaking PDT often the Doctor will ask the nurse to target sun damage spots with ablative laser. We find that this is associated with greater clearance of the sun damage spots and a better cosmetic outcome.

If the doctor has asked you to shave the area - make sure you shave 1-2 days before. It will be quite painful to have the procedure performed on newly shaved skin

Do not wear any makeup. Notify the doctor and dermal therapist if you have anything on your skin on your arrival
On arrival the doctor will discuss whether for you either to take your prescribed pain medication OR panadol or nurofen. Please tell the doctor if you are medically unable to take panadol or nurofen

***Consider being driven to and from this appointment due to the type of pain relief administered.**

The doctor will usually perform some nerve blocks. These are local anaesthetic injections into the face (if necessary). This is slightly uncomfortable and the dermal therapist will assist by pinching your skin elsewhere to distract you

After the nerve blocks -

Laser ablation is performed. Depending on the degree of sun damage the cream may be applied to solitary spots or an entire area of skin.

We use a cream called ALA or Metvix. The cream is applied to the skin and is stimulated by light which allows it to target and destroy sun damaged cells. The Doctor may highlight specific skin spots for the nurse to apply the cream, in very specific areas. In general we use the ALA cream for sun damage spots and Metvix for superficial type skin cancers.

Laser Ablation:

This is a minimally invasive procedure that utilises a precise, fractionated light beam to create microscopic controlled wounds to the skin. The laser works by targeting areas of concern whilst leaving surrounding tissue unaffected.
The laser creates a more precise pathway into the skin for increased efficacy.

Incubation:

The patient will then wait for a period of 1 or 3 hours in a dark room to allow the cream to penetrate the skin without further activation by light. The amount of time will be directed by the doctor and will depend on the type of lesion.

While you are waiting - You will be given a button to press if you have any concerns. Ensure you know where the button is before the nurse or therapist leaves the room.
The staff may from time to time come in and check on you - but if you have any concerns you must press the button. Do not rely on intermittent checking as the staff may be busy.

Light therapy:

The cream is then exposed to light via LED diode for up to aprox 8 mins.

The dermal therapist or nurse will place goggles over your eyes but the light will still be very intense. The light will not harm your eyes.

This is the most painful part of the procedure. People can differ in terms of how they experience pain, but some will find this very intense and "like burning of the skin". This is why the nerve blocks are performed and also why we recommend you take strong pain relief on your arrival.

In a minority of patients who are on antidepressants, the interaction of LED light and the medication may cause some slight bluriness of vision for around 30 minutes. This will resolve but you may consider delaying your departure from the clinic and plan accordingly if you feel unsafe to drive.

The treatment area then needs to be protected from light exposure during recovery for at least 48 hours. The area of treated skin will have some redness, stinging, peeling and may occasionally weep. This is entirely normal.

What to expect:

● Recovery: For field treatment of sun damage spots, recovery takes approximately 7 days. With redness lasting up to a few weeks.

● Pain (common): Usually mild burning sensation – sometimes more intense. Local anaesthetic is often used to limit discomfort and this will be done by the treating doctor. Pain is usually much shorter duration and less severe than for surgery or efudix treatment.

● Redness (common): Usually lasts up to a few weeks; and will be easing by the end of the first week

● Swelling (common): Usually lasts several days.

● Pustules (common): Tiny white pustules are common, and are not an indication of infection. These disappear over several days.

● Blistering and ulceration is uncommon
Medium to longer-term side effects may include:

● Hyperpigmentation (common): The skin in the treated site may be darker than the surrounding skin (like an area of dark tan) for several months. It usually settles spontaneously, and can be improved faster with fading creams if needed.

● Hypopigmentation (uncommon): The treated area may be paler than the surrounding skin.

● Scarring (rare): True scarring is rare. There may however be a tiny scar from the biopsy done to diagnose the lesion.

● Further treatment: If we are using PDT for treatment of a superficial skin cancer you will be reassessed at 3 months to determine if a second treatment is required. This is required for 20 - 30% of superficial skin cancer cases. BCC PDT needs to be repeated at the one week interval.

What are the alternatives:

● Laser resurfacing provides the best cosmetic result as it markedly reduces sun damage to both DNA & addresses wrinkles & pigmentation.
● Cryotherapy with liquid nitrogen
● Efudix
● Aldara

Further safety information:

CONTRAINDICATIONS:
Hypersensitivity to the active substance or to any of the excipients including arachis oil (peanut oil); Morpheaform basal cell carcinoma; Invasive squamous cell carcinoma of the skin; Porphyria.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:
General Direct eye contact should be avoided. Metvix cream should not be applied to the eyelids and mucous membranes. Methyl aminolevulinate may cause sensitization by skin contact resulting in angioedema, application site eczema or allergic contact dermatitis. The excipients cetostearyl alcohol and arachis oil may rarely cause local skin reactions (e.g. contact dermatitis), methyl- and propylhydroxybenzoate may cause allergic reactions (possibly delayed). Any UV-therapy should be discontinued before treatment. As a general precaution, sun exposure on the treated lesion sites and surrounding skin has to be avoided for a couple of days following treatment. In patients with a history of hypertension, pain during illumination may induce increased blood pressure. It is thus recommended to measure blood pressure in these patients who experience severe pain, and interrupt illumination (in addition to taking specific measures when needed) if these patients also present severe hypertension. Metvix with red LED light should only be administered in the presence of a physician, a nurse or other health care professionals trained in the use of photodynamic therapy with Metvix. Minimum effective dose is not defined. Conventional Photodynamic Therapy (PDT) with

a red-light lamp may be a precipitating factor for transient global amnesia in very rare instances. Although the exact mechanism is not known, stress and pain associated with illumination with the lamp may increase the risk to develop transient amnesia. If signs of confusion or disorientation are observed, PDT must be discontinued immediately. Actinic keratosis There is no histological confirmation on clearance of lesions nor data on patients previously treated with 5FU or tretinoin. There is no experience of treating pigmented or highly infiltrating lesions with Metvix. Thick (hyperkeratotic) actinic keratoses should not be treated with Metvix. There is limited experience from post-authorisation exposure in treating actinic keratoses in transplant patients on immunosuppressive therapy. A close monitoring of these patients, with re-treatment if necessary is recommended in this population. Basal cell carcinoma The efficacy of Metvix in treating basal cell carcinomas that have recurred following previous treatment has not been determined. Therefore, Metvix should only be used in the treatment of primary lesions. There is no experience in treating basal cell carcinomas associated with xeroderma pigmentosum, Gorlin's syndrome or immunosuppressive therapy. The sites of successfully treated lesions should be reviewed at 6-12 monthly intervals to detect recurrence. Squamous cell carcinoma in situ (Bowen's disease) There is no experience of treating lesions which are pigmented, highly infiltrating or located on the genitalia with Metvix cream. There is no experience of treating Bowen´s disease lesions larger than 40 mm in diameter. The sites of successfully treated lesions should be reviewed at 6-12 monthly intervals to detect recurrence.

The efficacy of Metvix in treating Bowen's disease lesions that have recurred following previous treatment has not been determined. Therefore, Metvix should only be used in the treatment of primary lesions. There is limited experience from post-authorisation exposure in treating Bowen´s disease in transplant patients on immunosuppressive therapy. A close monitoring of these patients, with re-treatment if necessary is recommended in this population. Use in hepatic impairment No information is available on the use of Metvix in this population. Use in renal impairment No information is available on the use of Metvix in this population. Use in the elderly No dosage adjustment required. Paediatric Use There is no experience of treating patients below the age of 18 years. Metvix is not recommended for use in children. Effects on laboratory tests No data available.

INTERACTIONS WITH OTHER MEDICINES: No specific interaction studies have been performed with Metvix.

FERTILITY, PREGNANCY AND LACTATION: Effects on Fertility Studies on the reproductive toxicity of methyl aminolevulinate have not been performed. Use in pregnancy – Pregnancy Category B2 No clinical data on exposed pregnancies are available for methyl aminolevulinate. No reproductive studies in animals have been performed. The potential risk is unknown. Methyl aminolevulinate is not recommended during pregnancy. Use in Lactation There are no human data on the excretion of methyl aminolevulinate in human breast milk or on the safety of methyl aminolevulinate exposure in newborns/infants following topical application of Metvix. A risk to the newborns/infants cannot be excluded. Therefore, breastfeeding should be discontinued for 48 h after application of Metvix.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES: No effects on ability to drive and use machines have been observed.

ADVERSE EFFECTS (UNDESIRABLE EFFECTS):

Between 60% and 80% of patients in clinical trials using conventional Photodynamic Therapy (c-PDT) experienced reactions localised to the treatment site that are attributable to the toxic effects of the photodynamic therapy (phototoxicity) or to the preparation of the lesion. The most frequent symptoms are painful and burning skin sensation typically beginning during illumination or soon after and lasting for a few hours with resolution on the day of treatment. The severity is usually mild or moderate, but rarely, it may require early termination of illumination. The most frequent signs of phototoxicity are erythema and oedema which may persist for 1 to 2 weeks or occasionally for longer. In two cases they persisted for more than one year. Table 1: Incidence of Local Adverse Reactions – Clinical Trials (c-PDT) Skin and subcutaneous tissue disorders Very common (>1/10) Pain and discomfort described as pain, burning, warm, stinging, pricking and tingling skin, erythema, itching, oedema Common (>1/100, < 1/10) Crusting, ulceration, blisters, suppuration, infection peeling, application site reactions, bleeding skin, hypo/hyperpigmentation Uncommon (>1/1000 <1/100) Rash, urticaria, eczema, skin irritation The following non-local adverse events were reported in clinical trials (c-PDT):

Nervous system disorders Uncommon: headache, dizziness Eye disorders Uncommon: Eye pain, eye irritation, eye swelling Vascular disorders: Uncommon: Wound hemorrhage Gastrointestinal disorders Uncommon: Nausea General disorders and administration site conditions Uncommon: Fatigue There were also isolated reports of scar where a relationship to treatment was uncertain. Repeated use did not increase the frequency or intensity of the local phototoxic reactions. In the Australian study comparing DL-PDT to c-PDT, 39% of patients treated with daylight (versus 59% for patients treated with c-PDT) reported at least one treatment-related adverse effect, the most frequent (≥ 4.0%) being skin reaction, scab, photosensitivity reaction and skin pain.
Adverse Reactions:
Post Marketing (c-PDT) Application site eczema and allergic contact dermatitis have been described in post-marketing reports. Most cases were localised to the treatment area and were not severe. Erythema and swelling have been more extensive on rare occasions. Eyelid oedema, face oedema (swelling face), angioedema, hypertension and transient global amnesia (including confusional state and disorientation) have also been described in post-marketing reports. Reporting suspected adverse effects Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.