Surgery or PDT

Which would your patients choose?

Photodynamic therapy for AK, BCC and Bowen's

Now available for your patients at

exetermedical

What is photodynamic therapy (PDT)?

PDT is a non-invasive treatment for non-melanoma skin cancers (NMSCs).

Traditional options for treating NMSCs aren't always suitable for every patient, but now there is a viable alternative available in your area.

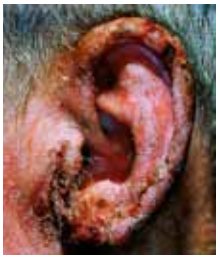
Using a combination of Metvix (methyl aminolevulinate) cream, red light and molecular oxygen, Metvix PDT is a non-surgical procedure, which preferentially targets tumour cells leaving healthy skin unaffected.[1-3]

Indications

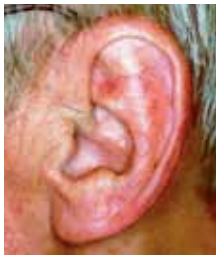
Metvix is the only topical treatment licensed for use in PDT. It has proven efficacy in actinic keratosis (AK), basal cell carcinoma (BCC) and Bowen's disease (squamous cell carcinoma in situ):

- **Actinic keratosis:** 93% overall lesion response after 1 treatment cycle[4]
- **BCC:** 89% complete response rate at 3-6 months[5]
- **Bowen's disease:** 93% complete response rate at 3 months[6]

Patient with AK

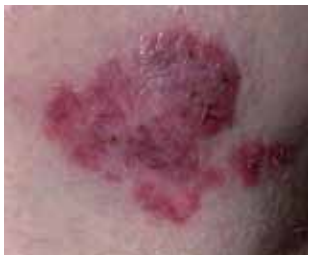


Before
Metvix

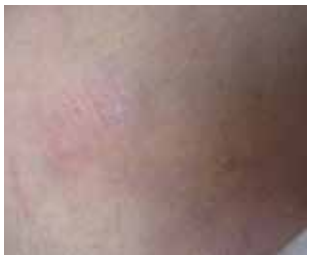


After
Metvix
(3 months)

Patient with Bowen's disease



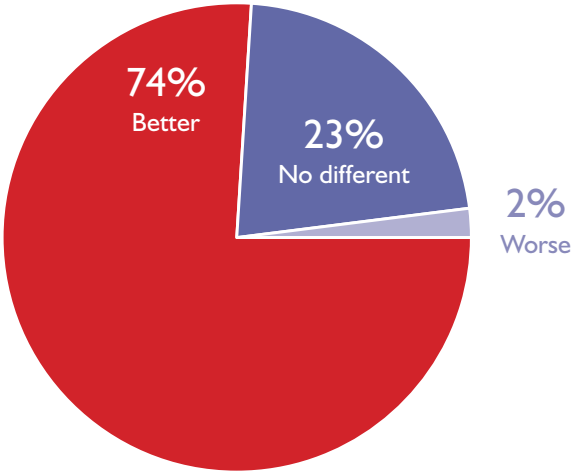
Before
Metvix



After
Metvix
(6 months)

METVIX PDT – Preferred by patients

Patients' rating of Metvix (on AKs) vs previous treatments
(n=43 previously treated*)[7]



(2 treatment sessions)

Adapted from Szeimies RM *et al*[7]
* Patients were mostly previously treated with cryotherapy and 5-FU (fluorouracil)

Metvix PDT has several features that appeal to patients:

- ☑ **non-invasive** procedure, does not require an over-night hospital stay, general anaesthetic or recovery time
- ☑ **excellent cosmetic results**, with 98% of patients and 96% of investigators rating the cosmetic outcome as 'excellent' or 'good'[7]
- ☑ **minimal downtime**, as Metvix PDT is a therapy option that fits well into patients' busy lives – a single session for AK and only 2 sessions, 7 days apart for BCC or Bowen's[8]
- ☑ **controlled** treatment that only targets affected areas, leaving healthy skin cells intact[1-3]

PDT is recommended by NICE in the treatment of NMSC

PDT is covered by NICE Interventional Procedure Guidance 155[9]

2010 NICE guidance on the management of BCC in the community states that in the case of superficial BCC, **"GPs should ensure that their patient is offered the full range of medical treatments (including, for example photodynamic therapy)"**[10]

metvix® PDT
methyl aminolevulinate
Precisely Directed Treatment

Refer your NMSC patients for Metvix photodynamic therapy, now at:

exetermedical

Exeter Medical Limited
Admiral House, Grenadier Road, Exeter Business Park,
Exeter, Devon, EX1 3QF
Tel: **01392 36 35 34** Fax: **01392 35 00 50**
Web: www.exetermedical.co.uk Email: info@exetermedical.co.uk

References: 1. Siddiqui MA. *Am J Clin Dermatol* 2004;**5**(2):127-137. **2.** Gardlo K & Ruzicka T. *Curr Op Inv Drugs* 2002;**3**:1672-1678. **3.** Angell-Peterson E. *et al. J Inv Dermatol* 2006;**126**:265-271. Published online December 2005. **4.** Tarstedt M *et al. Acta Derm Venereol* 2005;**85**:424-428. **5.** Soler AM *et al. Brit J Dermatol* 2001;**145**:467-471. **6.** Morton C *et al. Arch Dermatol* 2006;**142**(6):729-735. **7.** Szeimies RM *et al. J Am Acad Dermatol* 2002; **47**(2):258-262. **8.** Metvix Summary of Product Characteristics. October 2011. **9.** NICE Interventional Procedure Guidance 155. February 2006. **10.** NICE Guidance on Cancer Services. Improving Outcomes for People with Skin Tumours including Melanoma (update): The Management of Low-Risk Basal Cell Carcinomas in the Community. May 2010.

Metvix 160 mg/g cream Abbreviated Prescribing Information
Presentation: Cream containing 160 mg/g of methyl aminolevulinate (as hydrochloride) **Indications:** Treatment of thin or non-hyperkeratotic and non-pigmented actinic keratoses on the face and scalp when other therapies are considered less appropriate. Only for treatment of superficial and/or nodular basal cell carcinoma unsuitable for other available therapies due to possible treatment related morbidity and poor cosmetic outcome; such as lesions on the mid-face or ears, lesions on severely sun damaged skin, large lesions, or recurrent lesions. Treatment of squamous cell carcinoma in situ (Bowen's disease) when surgical excision is considered less appropriate. **Dosage and administration:** For treatment of actinic keratoses (AK) one session of photodynamic therapy should be administered. For treatment of basal cell carcinoma (BCC) two sessions should be administered with an interval of one week between sessions. Before applying Metvix cream, the surface of AK and superficial BCC lesions should be prepared to remove scales and crusts and roughen the surface of the lesions. Nodular BCC lesions are often covered by an intact epidermal keratin layer which should be removed. Exposed tumour material should be removed gently without any attempt to excise beyond the tumour margins. Apply Metvix cream (about 1 mm thick) using a spatula to the lesion and surrounding 5-10 mm of normal skin. Cover the treated area with an occlusive dressing for 3 hours. Remove dressing, and clean with saline and immediately expose the lesion to red light with a continuous spectrum of 570-670 nm and a total light dose of 75 J/cm^2. Multiple lesions may be treated during the same treatment session. Lesion response should be assessed after three months, and it is recommended to confirm the response of BCC lesions by histological biopsy. AK and BCC lesion sites that show non-complete response may be retreated if desired. Please refer to summary of product characteristics before use. There is no experience of treating patients below the age of 18 years. **Contraindications:** Hypersensitivity to the active or excipients which includes arachis oil. Morpheaform basal cell carcinoma. Porphyria. **Precautions and Warnings:** Should only be administered in the presence of a health care professional trained in the use of photodynamic therapy with Metvix. Not recommended during pregnancy. There is no experience of treating pigmented or highly infiltrating lesions with Metvix cream. Thick (hyperkeratotic) actinic keratoses should not be treated with Metvix. Methyl aminolevulinate may cause sensitization by skin contact. The excipient cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis), methyl- and propylparahydroxybenzoate (E218, E216) 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. Direct eye contact with Metvix cream should be avoided. **Pregnancy and lactation:** Metvix is not recommended during pregnancy. In the absence of clinical experience, breast-feeding should be discontinued for 48 hours after application of Metvix cream. **Undesirable effects:** a) Approximately 60% of patients experience reactions localised to the treatment site that are attributable to toxic effects of the photodynamic therapy (phototoxicity) or to 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 resolving on the day of treatment. The symptoms are usually of mild or moderate severity and rarely require early termination of illumination. The most frequent signs of phototoxicity are erythema and scab. The majority are of mild or moderate severity and persist for 1 to 2 weeks or occasionally longer. Repeated treatment with Metvix is associated reduced frequency and severity of local phototoxic reactions. b) The incidence of adverse reactions in a clinical trial population of 932 patients receiving the standard treatment regimen, is shown in the table below.

Body system (MedDRA)	Frequency	Adverse reaction
Nervous system disorders	Common (≥1/100, <1/10)	Paraesthesia, headache
Eye disorders	Uncommon (≥1/1000, ≤1/100)	Eye swelling, eye pain
Vascular disorders	Uncommon (≥1/1000, ≤1/100)	Wound haemorrhage
Gastrointestinal disorders	Uncommon (≥1/1000, ≤1/100)	Nausea
Skin and subcutaneous tissue disorders	Very common (≥1/10)	Pain of skin, skin burning sensation, scab, erythema
	Common (≥1/100, <1/10)	Skin infection, skin ulcer, skin oedema, skin swelling, blister, skin hemorrhage, pruritus, skin exfoliation, skin warm
	Uncommon (≥1/1000, ≤1/100)	Urticaria, rash, skin irritation, photosensitivity reaction, skin hypopigmentation, heat rash, skin discomfort
General disorders and administration site conditions	Common (≥1/100, <1/10)	Application site discharge, feeling hot
	Uncommon (≥1/1000, ≤1/100)	Fatigue

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; rarely erythema and swelling have been more extensive. A study conducted in immunocompromised organ transplant recipients did not identify any safety concern in this population, adverse events being similar to those reported in trials in immunocompetent patients. **MA Numbers:** PL 10590/0048 (UK) & PA 590/20/1 (Ireland). **Packaging Quantities and Cost:** Tube of 2 gram, UK - £199.00 (NHS), Ireland - €295.95. **Legal Category:** POM **Full Prescribing Information is Available From:** Galderma (UK) Limited, Meridien House, 69-71 Clarendon Road, Watford, Herts. WD17 1DS, UK. Tel: +44 (0) 1923 208950 Fax: +44 (0) 1923 208998. **Date of Revision:** March 2011

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Galderma (UK) Ltd.

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Date of Preparation: April 2012

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