



## Efudix

### PRODUCT SUMMARY

- 1. Trade Name of the Medicinal Product**  
Efudix cream contains the substance with the approved name fluorouracil. It is chemically described as 5-fluorouracil.
- 2. Qualitative and Quantitative Composition**  
Efudix cream contains 5% w/w fluorouracil.
- 3. Pharmaceutical Form**  
White, opaque cream containing 5% w/w fluorouracil.

### CLINICAL PARTICULARS

#### 4.1 Therapeutic Indications

Efudix is used for the topical treatment of superficial pre-malignant and malignant skin lesions; keratoses including senile, actinic and arsenical forms; keratoacanthoma; Bowen's disease; superficial basal-cell carcinoma. Deep, penetrating or nodular basal cell and squamous cell carcinomas do not usually respond to Efudix therapy. It should be used only as a palliative therapy in such cases where no other form of treatment is possible.

#### 4.2 Posology and Method of Administration

Efudix cream is for topical application.

##### *Pre-malignant conditions*

The cream should be applied thinly to the affected area once or twice daily; an occlusive dressing is not essential.

##### *Malignant conditions*

The cream should be applied once or twice daily under an occlusive dressing where this is practicable.

The cream should not harm healthy skin. Treatment should be continued until there is marked inflammatory response from the treated area, preferably with some erosion in the case of pre-malignant conditions. Severe discomfort may be alleviated by the use of topical steroid cream. The usual duration of treatment for an initial course of therapy is three to four weeks, but this may be prolonged. Lesions on the face usually respond more quickly than those on the trunk or lower

limbs whilst lesions on the hands and forearms respond more slowly. Healing may not be complete until one or two months after therapy is stopped.

#### *Elderly*

Many of the conditions for which Efudix is indicated are common in the elderly. No special precautions are necessary.

#### *Children*

In view of the lack of clinical data available, Efudix is not recommended for use in children.

#### **4.3 Contra-indications**

Efudix is contra-indicated in patients with known hypersensitivity to Efudix or parabens.

#### **4.4 Special Warnings and Precautions for Use**

Efudix is for topical use only and care should be taken to avoid contact with mucous membranes or the eyes. The hands should be washed carefully after applying the cream.

The total area of skin being treated with Efudix at any one time should not exceed 500cm<sup>2</sup> (approx. 23 x 23cm). Larger areas should be treated a section at a time.

#### **4.5 Interactions with other Medicaments and other forms of Interaction**

No significant drug interactions with Efudix have been reported.

#### **4.6 Pregnancy and Lactation**

There is evidence from animal work that fluorouracil is teratogenic and there is no evidence as to drug safety in human pregnancy. Therefore the use of Efudix is contra-indicated during pregnancy. It should also be regarded as contra-indicated in mothers who are breast-feeding.

#### **4.7 Effects on Ability to Drive and Use Machines**

None known.

#### **4.8 Undesirable Effects**

Efudix is well tolerated. Transient erythema may occur in healthy skin surrounding the area being treated. Pre-existing subclinical lesions may become apparent. Exposure to sunlight may increase the intensity of the reaction. Dermatitis, allergic skin reactions and, rarely, erythema multiforme have been reported.

*Percutaneous absorption* of fluorouracil should not lead to clinically significant systemic toxicity when Efudix is administered as directed. However, this possibility should be borne in mind if the product is used excessively, especially on ulcerated or broken skin.

#### **4.9 Overdose**

If Efudix is accidentally ingested, signs of fluorouracil overdosage may include nausea, vomiting and diarrhoea. Stomatitis and blood dyscrasias may occur in

severe cases. Appropriate measures should be taken for the prevention of systemic infection and daily white cell counts should be performed.

## **PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic Properties**

Efudix is a topical cytostatic preparation which exerts a beneficial therapeutic effect on neoplastic and pre-neoplastic skin lesions without damaging normal skin. The pattern of response follows this sequence: erythema, vesiculation, erosion, ulceration, necrosis and epithelisation.

### **5.2 Pharmacokinetic Properties**

Animal studies have shown that after topical application of fluorouracil, less than 10% is systemically absorbed. This may be metabolised by catabolic or anabolic routes which are similar to that of endogenous uracil.

## **PHARMACEUTICAL PARTICULARS**

### **6.1 List of Excipients**

Cetostearyl Alcohol HSE  
White Soft Paraffin BP  
Polysorbate 60 EP  
Propylene Glycol EP  
Methyl Parahydroxybenzoate EP  
Propyl Parahydroxybenzoate EP  
Purified Water EP

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf Life**

The recommended shelf life of Efudix cream is 60 months.

### **6.4 Special Precautions for Storage**

#### *Storage*

The recommended maximum storage temperature for Efudix cream is 30°C.

#### *Dilution*

Efudix cream should not be diluted.

### **6.5 Nature and Contents of Container**

Efudix cream is supplied in an aluminium tube with a plastic screw cap.

### **6.6 Instruction for Use/Handling**

Efudix is for topical use only and care should be taken to avoid contact with mucous membranes or the eyes. The hands should be washed carefully after applying the cream.

#### **ADMINISTRATIVE DATA**

- 7. Marketing Authorisation Holder**  
ICN Pharmaceuticals Limited  
Cedarwood  
Chineham Business Park  
Crockford Lane  
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- 8. Marketing Authorisation Number**  
PL 15142/0003
- 9. Date of (Partial) Revision of Text**  
March 2000

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