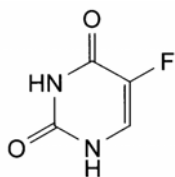


PRODUCT INFORMATION

EFUDIX



Fluorouracil

CAS number: 51-21-8

Description:

An oil-in-water emulsion containing Fluorouracil 5% w/w. Efudix also contains the excipients methyl hydroxybenzoate, paraffin-soft white, polysorbate 60, propyl hydroxybenzoate, propylene glycol, stearyl alcohol and water – purified.

Action:

When the preparation is applied to keratotic and preneoplastic lesions it produces the following pattern of response: first erythema, then, usually, vesiculation, erosion, ulceration, necrosis and epithelialisation.

Indications:

Solar and senile keratoses, Bowen's disease.

Contra-indications:

Efudix[®] should not be used in patients with dihydropyrimidine dehydrogenase (DPD) enzyme deficiency. A large percentage of fluorouracil is catabolized by the enzyme dihydropyrimidine dehydrogenase (DPD). DPD enzyme deficiency can result in shunting of fluorouracil to the anabolic pathway, leading to cytotoxic activity and potential toxicities.

Rarely, life-threatening toxicities such as stomatitis, diarrhoea, neutropenia, and neurotoxicity have been reported with intravenous administration of fluorouracil in patients with DPD enzyme deficiency.

A case of life-threatening systemic toxicity has been reported with the topical use of fluorouracil 5% in a patient with DPD enzyme deficiency. Symptoms included severe abdominal pain, bloody diarrhoea, vomiting, fever, and chills. Physical examination revealed stomatitis, erythematous skin rash, neutropenia, thrombocytopenia, inflammation of the esophagus, stomach, and small bowel. Although this case was observed with 5% fluorouracil cream, it is unknown whether patients with profound DPD enzyme deficiency would develop systemic toxicity with lower concentrations of topically applied fluorouracil.

Known hypersensitivity to Efudix.

Precautions:

Highly irritant and so should not be allowed to come in contact with mucous membranes or the eyes. Treatment of perioral area or nasolabial fold should be avoided, or treated carefully. Because of its irritant nature, care should be taken to see that Efudix does not come into contact with normal skin. Efudix should be applied with a non-metal applicator or rubber glove. Should a glove not be worn and the hands come in contact with Efudix during application they should be washed thoroughly. Efudix therapy is not advisable in persons who work outdoors for prolonged periods in the sun. Excessive sun exposure may produce a diffuse phototoxic response in the areas of application. While treatment is in progress, avoid: Cosmetics on treated areas; other topical medication applied to the same area, unless otherwise directed.

Use in Pregnancy:

Category D. Contra-indicated in pregnancy or where pregnancy cannot be excluded.

Adverse Reactions:

The most frequently encountered local reactions have been pain, pruritus, hyperpigmentation, and burning at the site of application. Other local reactions include dermatitis, scarring, soreness and tenderness. The patient should be advised of the temporary unsightly appearance and local discomfort to be expected during treatment with this drug. Patients with chloasma and rosacea and other inflammatory dermatoses may encounter accentuation of their condition and should first be treated with appropriate therapy before using the medication. While absorption of Efudix through healthy skin is negligible, absorption is considerably increased when it is applied to diseased skin. However, clinical experience has not demonstrated any adverse systemic toxicity nor haematological side effects.

Dosage and Administration:

Efudix should only be used under medical supervision. In cases of senile and solar keratoses a thin layer of the cream is applied to the affected areas once or twice daily, generally without a dressing. In the treatment of other conditions (including keratosis palmaris) a fresh occlusive dressing should be applied daily. Treatment should be continued up to the erosion stage. Duration of therapy is usually 3-4 weeks, but it may prove necessary to exceed this on occasion. When Efudix is applied to the skin, the following usually happens: a redness of the affected area (generally within 3 to 5 days) followed by blistering, peeling, and cracking (within 11 to 14 days) with occasional open sores and some discomfort. Although the skin seems to be worse, it is a sign that the medication is working. The treated skin will flake away. Some redness of the skin will continue for some time after the drug is stopped.

Limitation of Treatment Area:

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

Tolerance:

Efudix is well tolerated. The healthy skin surrounding the area being treated may occasionally become reddened, but soon resumes its normal colour on cessation of treatment.

Presentation and Storage Conditions:

Fluorouracil 5% w/w cream: 20 g aluminium tube.

Storage:

Store below 30°C. Shelf life: 5 years.

AUST R 13721.

Sponsor:

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