IMPORTANT SAFETY INFORMATION FOR EFUDEX® (FLUOROURACIL) CREAM, 5%

INDICATION

EFUDEX is recommended for the topical treatment of multiple actinic or solar keratoses, and in the treatment of superficial basal cell carcinoma when conventional methods are impractical, such as with multiple lesions or difficult treatment sites.

The diagnosis should be established prior to treatment, since this method has not been proven effective in other types of basal cell carcinoma. With isolated, easily accessible basal cell carcinomas, surgery is preferred, with a success rate of almost 100%.

IMPORTANT SAFETY INFORMTION

- **Due to the potential to cause harm to the fetus, EFUDEX is contraindicated in women who are or may become pregnant during therapy. If pregnancy occurs during treatment, the patient must be apprised of the potential harm.**
- EFUDEX should not be used in patients with dihydropyrimidine (DPD) enzyme deficiency due to potential for rare, life-threatening toxicity, or in patients with known hypersensitivity to any of its components. If symptoms of severe abdominal pain, bloody diarrhea, vomiting, fever, and chills occur, discontinue treatment.
- **Application to mucous membranes should be avoided due to the possibility of local inflammation and ulceration. Additionally, miscarriage and birth defect have been reported when EFUDEX was applied to mucous membranes during pregnancy.**
- Use under occlusive dressing may cause an increase in the severity of inflammatory reactions in adjacent normal skin.
- Exposure to ultraviolet rays should be minimized during and immediately following treatment due to potential for increased inflammatory reaction.
- Rarely, life-threatening toxicities such as stomatitis, diarrhea, neutropenia, and neurotoxicity have been reported with IV administration in patients with DPD enzyme deficiency.
- The most frequent adverse reactions occur locally and include burning, crusting, allergic contact dermatitis, pruritus, scarring, rash, soreness, and ulcerations.

To report SUSPECTED ADVERSE REACTIONS, contact customer service at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please click here for full Prescribing Information

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