Carac® is indicated for the topical treatment of multiple actinic or solar keratoses of the face and anterior scalp.

CONTRACINDICATIONS
Carac is contraindicated for use in the following conditions:

- Pregnancy.
- Nursing.
- Women under 18 years of age.
- Men with a past or present history of a cardiac valve disorder.
- Men with a history of a left ventricular aneurysm.
- Patients with severe skin reactions such as contact dermatitis.
- Patients with a history of actinic keratosis.
- Patients with a history of sun sensitivity.
- Patients with a history of skin cancer.
- Patients with a history of skin neoplasia.
- Patients with a history of a severe allergic reaction to any component of Carac.
- Patients with a history of a severe allergic reaction to any component of vehicle.

WARNINGS
- Do not use Carac if you are pregnant or might become pregnant.
- Do not use Carac if you are nursing.
- Do not use Carac if you are under 18 years of age.
- Do not use Carac if you have a past or present history of a cardiac valve disorder.
- Do not use Carac if you have a history of a left ventricular aneurysm.
- Do not use Carac if you have severe skin reactions such as contact dermatitis.
- Do not use Carac if you have a history of actinic keratosis.
- Do not use Carac if you have a history of sun sensitivity.
- Do not use Carac if you have a history of skin cancer.
- Do not use Carac if you have a history of skin neoplasia.
- Do not use Carac if you have a severe allergic reaction to any component of Carac.
- Do not use Carac if you have a severe allergic reaction to any component of vehicle.

ADVERSE REACTIONS
- Local reactions: Most common local reactions reported with Carac are skin irritation, erythema, and dryness. Other local reactions reported include burning, itching, pain, and pruritus.

- Systemic reactions: The most common systemic reactions reported with Carac are fatigue, nausea, and vomiting. Other systemic reactions reported include fever, chills, hypotension, and edema.

- Other reactions: The most common other reactions reported with Carac are headache, dizziness, and drowsiness.

- Other abnormal laboratory findings: The most common abnormal laboratory findings reported with Carac are elevated transaminases, elevated alkaline phosphatase, and elevated creatine phosphokinase.

- Other clinical laboratory findings: The most common other clinical laboratory findings reported with Carac are increased creatinine, increased uric acid, and increased blood urea nitrogen.

- Other adverse reactions: The most common other adverse reactions reported with Carac are allergic reactions, including contact dermatitis, and infections, including fungal infections.

- Other serious adverse reactions: The most common other serious adverse reactions reported with Carac are death, respiratory failure, and cardiac arrest.

- Other rare adverse reactions: The most common other rare adverse reactions reported with Carac are anaphylaxis, angioedema, and Stevens-Johnson syndrome.

- Other severe reactions: The most common other severe reactions reported with Carac are Stevens-Johnson syndrome, toxic epidermal necrolysis, and anaphylaxis.

- Other rare reactions: The most common other rare reactions reported with Carac are allergic reactions, including contact dermatitis, and infections, including fungal infections.

- Other serious reactions: The most common other serious reactions reported with Carac are death, respiratory failure, and cardiac arrest.

- Other adverse effects: The most common other adverse effects reported with Carac are allergic reactions, including contact dermatitis, and infections, including fungal infections.

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To rule out the presence of a frank neoplasm, a biopsy may be considered for those areas failing to respond to treatment or recurring

Adequate long-term studies in animals to evaluate carcinogenic potential have not been performed. However, the animal carcinogenic potential of Fluorouracil (5-fluorouracil) has been studied in the rat and mouse, and there is some indication that Fluorouracil (5-fluorouracil) is capable of inducing tumors at affected sites. The role of non-activated metabolites of Fluorouracil (5-fluorouracil) in the tumorigenic process is not fully understood.

No evidence of mutagenic potential for Fluorouracil (5-fluorouracil) has been shown. The Ames test with an S. typhimurium strain has been negative, and Fluorouracil (5-fluorouracil) has been shown to be non-mutagenic in the bacterial test and in the mouse micronucleus test.

There is no evidence of genotoxic potential for Fluorouracil (5-fluorouracil), including in vitro experiments using Chinese hamster ovary (CHO) cells and in vivo experiments using bone marrow cells from mice. In cell-free extracts of CHO cells treated with Fluorouracil (5-fluorouracil), some mutagenic activity has been shown, but the active metabolites of Fluorouracil (5-fluorouracil) have not been isolated. In studies of sister chromatid exchange (SCE) and chromosomal aberration, Fluorouracil (5-fluorouracil) has been negative in rodent and human cells.

Rats and mice treated with Fluorouracil (5-fluorouracil) have shown an increased incidence of chromosomal abnormalities in bone marrow cells and spermatids, primarily at the dose levels of 50 and 100 mg/kg. Some of these abnormalities are those that accompany radiation damage. These findings are consistent with the ability of Fluorouracil (5-fluorouracil) and its active metabolites to cause cell killing and non-killing DNA damage. In vivo studies have also shown that Fluorouracil (5-fluorouracil) induces single-strand breaks in DNA in rat bone marrow cells. Studies in vitro have shown that Fluorouracil (5-fluorouracil) and its metabolites are mutagenic in the Ames test with an S. typhimurium strain. These findings suggest that Fluorouracil (5-fluorouracil) may be mutagenic in vivo.

Rats, mice, and hamsters treated with Fluorouracil (5-fluorouracil) have shown an increased incidence of reproductive and developmental disorders, including sterility, early embryonic death, congenital abnormalities, and birth defects. In these studies, Fluorouracil (5-fluorouracil) was administered in the diet, and the dose levels were high enough to cause significant maternal toxicity. In these studies, Fluorouracil (5-fluorouracil) was administered in the diet, and the dose levels were high enough to cause significant maternal toxicity. In these studies, Fluorouracil (5-fluorouracil) was administered in the diet, and the dose levels were high enough to cause significant maternal toxicity. In these studies, Fluorouracil (5-fluorouracil) was administered in the diet, and the dose levels were high enough to cause significant maternal toxicity. In these studies, Fluorouracil (5-fluorouracil) was administered in the diet, and the dose levels were high enough to cause significant maternal toxicity. In these studies, Fluorouracil (5-fluorouracil) was administered in the diet, and the dose levels were high enough to cause significant maternal toxicity. In these studies, Fluorouracil (5-fluorouracil) was administered in the diet, and the dose levels were high enough to cause significant maternal toxicity. In these studies, Fluorouracil (5-fluorouracil) was administered in the diet, and the dose levels were high enough to cause significant maternal toxicity. In these studies, Fluorouracil (5-fluorouracil) was administered in the diet, and the dose levels were high enough to cause significant maternal toxicity. In these studies, Fluorouracil (5-fluorouracil) was administered in the diet, and the dose levels were high enough to cause significant maternal toxicity. In these studies, Fluorouracil (5-fluorouracil) was administered in the diet, and the dose levels were high enough to cause significant maternal toxicity. In these studies, Fluorouracil (5-fluorouracil) was administered in the diet, and the dose levels were high enough to cause significant maternal toxicity. In these studies, Fluorouracil (5-fluorouracil) was administered in the diet, and the dose levels were high enough to cause significant maternal toxicity. In these studies, Fluorouracil (5-fluorouracil) was administered in the diet, and the dose levels were high enough to cause significant maternal toxicity. In these studies, Fluorouracil (5-fluorouracil) was administered in the diet, and the dose levels were high enough to cause significant maternal toxicity. In these studies, Fluorouracil (5-fluorouracil) was administered in the diet, and the dose levels were high enough to cause significant maternal toxicity. In these studies, Fluorouracil (5-fluorouracil) was administered in the diet, and the dose levels were high enough to cause significant maternal toxicity. In these studies, Fluorouracil (5-fluorouracil) was administered in the diet, and the dose levels were high enough to cause significant maternal toxicity. In these studies, Fluorouracil (5-fluorouracil) was administered in the diet, and the dose levels were high enough to cause significant maternal toxicity. In these studies, Fluorouracil (5-fluorouracil) was administered in the diet, and the dose levels were high enough to cause significant maternal toxicity. In these studies, Fluorouracil (5-fluorouracil) was administered in the diet, and the dose levels were high enough to cause significant maternal toxicity. In these studies, Fluorouracil (5-fluorouracil) was administered in the diet, and the dose levels were high enough to cause significant maternal toxicity.

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