Allergan, Inc.

TAZORAC®

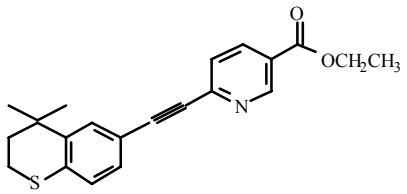
(tazarotene topical cream) 0.05%
(tazarotene topical cream) 0.1%

FOR DERMATOLOGIC USE ONLY

NOT FOR OPHTHALMIC USE

DESCRIPTION

TAZORAC® cream is available as a white emollient cream and contains the compound tazarotene, a member of the acetylenic class of retinoids. It is for topical dermatologic use only. The active ingredient is represented by the following structural formula:



TAZAROTENE

Formula: $C_{21}H_{21}NO_2S$ Molecular Weight: 351.46
Chemical Name: Ethyl 6-[2-(4,4-dimethylthiochroman-6-yl)ethynyl] nicotinate

Contains:

Active:	Tazarotene…….	0.05% or 0.1% (w/w)
Preservative:	Benzyl alcohol…….....	1.0% (w/w)
Inactives:	Carbomer 934P, carbomer 1342, edetate disodium, medium chain triglycerides, mineral oil, purified water, sodium thiosulfate, sorbitan monooleate and sodium hydroxide to adjust the pH.	

CLINICAL PHARMACOLOGY:

Tazarotene is a retinoid prodrug which is converted to its active form, the cognate carboxylic acid of tazarotene (AGN 190299), by rapid deesterification in animals and man. AGN 190299 ("tazarotenic acid") binds to all three members of the retinoic acid receptor (RAR) family: RARα, RARβ, and RARγ, but shows relative selectivity for RARβ, and RARγ and may modify gene expression. The clinical significance of these findings is unknown

The mechanism of tazarotene action in psoriasis is not defined. Topical tazarotene blocks induction of mouse epidermal ornithine decarboxylase (ODC) activity, which is associated with cell proliferation and expression. In cell culture and *in vitro* models of skin, tazarotene suppresses expression of MRP8, a marker of inflammation present in the epidermis of psoriasis subjects at high levels. In human keratinocyte cultures, it inhibits cornified envelope formation, whose build-up is an element of the psoriatic scale expression. Tazarotene also induces the expression of TIG3 (tazarotene-induced gene 3), a tumor suppressor, which may inhibit epidermal hyperproliferation in treated plaques Tazarotene, therefore, has multiple effects on keratinocyte differentiation and proliferation, as well as on inflammatory processes which contribute to the pathogenesis of psoriasis. The clinical significance of these findings is unknown.

Pharmacokinetics:
Following topical application, tazarotene undergoes esterase hydrolysis to form its active metabolite, tazarotenic acid. Little parent compound could be detected in the plasma. Tazarotenic acid was highly bound to plasma proteins (>99%). Tazarotene and tazarotenic acid were metabolized to sulfoxides, sulfones and other polar metabolites which were eliminated through urinary and fecal pathways. The half-life of tazarotenic acid following topical application of tazarotene was similar in normal and psoriatic subjects, approximately 18 hours.

In a 14-day study in 9 psoriatic patients, measured doses of tazarotene 0.1% cream were applied daily by medical staff to involved skin without occlusion (5 to 35% of total body surface area; mean ± SD: 14 ± 11 %). The Cmax of tazarotenic acid was 2.31 ± 2.78 ng/mL occurring 8 hours after the final dose, and the $AUC_{0\text{-}24hr}$ was 31.2 ± 35.2 ng·hr/mL in the five patients who were administered clinical doses of 2 mg cream/cm^2. At an exaggerated dosing rate of 10 mg cream/cm^2, the Cmax was 3.07 ± 2.63 ng/mL (N=4) occurring at 7 hours post dose, and the $AUC_{0\text{-}24hr}$ was 46.4 ± 37.6 ng·hr/mL. Both the recommended clinical dose and an exaggerated dose, i.e., 2 and 10 mg cream/cm^2, respectively, produced comparable systemic exposure of tazarotenic acid in psoriatic subjects. Systemic absorption was approximately 2-3% of the topically applied dose. Extrapolation of these results to represent dosing on 20% of total body surface under an exaggerated dosing regimen (i.e., 10 mg cream/cm^2) yielded estimates of Cmax of 6.04 ± 1.09 ng/mL and $AUC_{0\text{-}24hr}$ of 98.4 ± 18.6 ng·hr/mL.

During clinical trials with 0.05% or 0.1% tazarotene cream treatment, only three out of 139 patients with their systemic exposure monitored had detectable plasma tazarotene concentrations, with the highest value at 0.09 ng/mL. The majority of patients did not have measurable plasma tazarotenic acid concentrations, i.e. < 0.1 ng/mL. Only six patients had plasma tazarotenic acid concentrations greater than 1 ng/mL. The highest value was 2.4 ng/mL.

Results from the well-controlled clinical pharmacokinetic and therapeutic drug monitoring studies demonstrated limited systemic exposure after topical daily applications of tazarotene cream to psoriatic skin.

Clinical Studies:
In two 12-week vehicle-controlled clinical studies, tazarotene 0.05% and 0.1% creams were significantly more effective than vehicle in reducing the severity of plaque psoriasis. Tazarotene creams demonstrated effectiveness as early as 1 week after starting treatment, and initial treatment success (global response to treatment of moderate, marked, almost cleared or completely cleared) was reached significantly earlier than with vehicle. Treatment success rates with the 0.1% cream were generally superior (numerically) to those with the 0.05% cream.

During these studies, the number of patients with none, minimal or mild overall disease was significantly greater with tazarotene 0.05% and 0.1% vs vehicle at most follow-up visits.

In one of these studies, patients were also evaluated for 12 weeks following cessation of therapy, and it was found that subjects treated with the 0.05% and 0.1% tazarotene creams continued to show a therapeutic effect during the 12-week post-treatment period.

Improvements in plaque elevation, scaling, and erythema were generally significantly greater with tazarotene 0.05% and 0.1% than with vehicle. Tazarotene 0.1% was generally more effective than the 0.05% concentration in reducing the severity of the individual signs of disease. However, tazarotene 0.1% was associated with a somewhat greater degree of local irritation than the 0.05% cream.

Mean Decrease in Plaque Elevation, Scaling and Erythema in Two Controlled Clinical Trials for Psoriasis

		TAZORAC® 0.05% Cream						TAZORAC® 0.1% Cream						Vehicle Cream					
Lesion		Trunk/Arm/ Leg lesions		Knee/Elbow lesions		All Treated		Trunk/Arm/ Leg lesions		Knee/Elbow lesions		All Treated		Trunk/Arm/ Leg lesions		Knee/Elbow lesions		All Treated	
		N=218	N=210	N=218	N=210	N=218	N=210	N=221	N=211	N=221	N=211	N=221	N=211	N=229	N=214	N=229	N=214	N=229	N=214
Plaque elevation	**B***	**2.29**	**2.50**	**2.40**	**2.52**	**2.28**	**2.51**	**2.34**	**2.52**	**2.35**	**2.49**	**2.32**	**2.51**	**2.28**	**2.51**	**2.35**	**2.51**	**2.29**	**2.51**
	C-12*	-0.83*	-0.98*	-0.91*	-1.04*	-0.75*	-0.90*	-1.08*	-1.25*	-0.96*	-1.21*	-0.83*	-1.08*	-0.59	-0.69	-0.57	-0.68	-0.48	-0.61
	C-24*	-0.75*		-0.73*		-0.60*		-0.87*		-0.73*		-0.63*		-0.57		-0.49		-0.42	
Scaling	B*	**2.26**	**2.45**	**2.47**	**2.60**	**2.32**	**2.47**	**2.37**	**2.45**	**2.40**	**2.57**	**2.36**	**2.53**	**2.34**	**2.46**	**2.45**	**2.61**	**2.31**	**2.53**
	C-12*	-0.75*	-0.90*	-0.78*	-0.98*	-0.67*	-0.80*	-0.84*	-1.06*	-0.76*	-1.13*	-0.73*	-1.03*	-0.66	-0.79	-0.62	-0.76	-0.46	-0.70
	C-24*	-0.68*		-0.62*		-0.51*		-0.79*		-0.61*		-0.59*		-0.56		-0.45		-0.45	
Erythema	B*	**2.26**	**2.51**	**2.17**	**2.40**	**2.23**	**2.48**	**2.25**	**2.53**	**2.17**	**2.42**	**2.21**	**2.51**	**2.24**	**2.47**	**2.17**	**2.34**	**2.24**	**2.47**
	C-12*	-0.49*	-0.65*	-0.44*	-0.66*	-0.40*	-0.62*	-0.49*	-0.82*	-0.57*	-0.82*	-0.42*	-0.78*	-0.42	-0.46	-0.38	-0.44	-0.37	-0.47
	C-24*	-0.52*		-0.44*		-0.41*		-0.55*		-0.52*		-0.39*		-0.43		-0.34		-0.33	

Plaque elevation, scaling and erythema scored on a 0-4 scale with 0=none, 1=mild, 2=moderate, 3=severe and 4=very severe.

*B=Mean Baseline Severity:

C-12=Mean Change from Baseline at end of 12 weeks of therapy:

C-24=Mean Change from Baseline at week 24 (12 weeks after the end of therapy).

***Denotes statistically significant difference compared with vehicle**

Lesion	Study 1				Study 2			
	Taz 0.05% N = 218	Taz 0.1% N = 221	Vehicle N = 229	P-value	Taz 0.05% N = 210	Taz 0.1% N = 211	Vehicle N = 214	P-value
all treated								
C-12x	42.7%	48.9%	30.1%	< 0.001b	47.6%	58.8%	36.9%	< 0.001c
C-24y	38.5%	37.6%	27.1%	0.014b				
knee/elbow C-12x	45.4%	53.4%	30.6%	< 0.001b	53.3%	62.6%	39.3%	< 0.001b
C-24y	39.9%	39.4%	26.6%	0.004b				
trunk/limb								
C-12x	45.4%	51.1%	32.3%	< 0.001b	49.1%	56.9%	37.9%	< 0.001b
C-24y	40.4%	39.8%	30.6%	0.044b				

Treatment Success Rate[a] at Week 12 and 12 Weeks Post Treatment in Phase 3 Studies

Taz = tazarotene cream. N = number of patients at baseline; subsequent sample sizes may vary due to missing values.

a Treatment success rate = percent of patients with a global response to treatment of moderate, marked, almost cleared, or completely cleared.

b Pairwise comparisons favored tazarotene 0.1% and 0.05% vs vehicle.

c Pairwise comparisons favored tazarotene 0.1% and 0.05% vs vehicle, and favored tazarotene 0.1% vs 0.05%.

x C-12x=Value at end of 12 week study.

y C-24y=Value at 12 weeks post-treatment.

INDICATIONS AND USAGE:

TAZORAC® (tazarotene topical cream) 0.05% and 0.1% are indicated for the topical treatment of patients with plaque psoriasis.

CONTRAINDICATIONS:
Retinoids may cause fetal harm when administered to a pregnant woman.

In rats, tazarotene 0.05% **gel** administered **topically** during gestation days 6 through 17 at 0.25 mg/kg/day resulted in reduced fetal body weights and reduced skeletal ossification. Rabbits dosed **topically** with 0.25 mg/kg/day tazarotene **gel** during gestation days 6 through 18 were noted with single incidences of known retinoid malformations, including spina bifida, hydrocephaly, and heart anomalies. Systemic exposure at topical doses of 0.25 mg/kg/day in rats and rabbits represented 1.1 and 12 times, respectively, that in human psoriatic patients, when extrapolated for topical treatment of 0.1% tazarotene cream over a 20% body surface area.

As with other retinoids, teratogenic effects in rats and rabbits were observed when tazarotene was given **orally** at doses of 0.2-0.25 mg/kg/day. The 0.25 mg/kg/day dose in rats and 0.2 mg/kg/d dose in rabbits achieved tazarotenic acid Cmax of 51 ng/mL and 253 ng/mL, respectively, and AUC of approximately 115 ng·hr/mL and 2272 ng·hr/mL, respectively. Systemic exposure at **oral** doses of 0.25 mg/kg/day in rats and 0.2 mg/kg/day in rabbits represented 1.2 and 23 times, respectively, that in human psoriatic patients, when extrapolated for topical treatment of 0.1% tazarotene cream over a 20% body surface area.

Although there were no reported pregnancies during the tazarotene cream clinical trials, six pregnant women who were inadvertently exposed to tazarotene **gel** during clinical trials subsequently delivered healthy babies. As the exact timing and extent of exposure in relation to the gestation time are not certain, the significance of these findings is unknown.

TAZORAC® is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, treatment should be discontinued and the patient apprised of the potential hazard to the fetus. Women of child-bearing potential should be warned of the potential risk and use adequate birth-control measures when TAZORAC® is used. The possibility that a woman of childbearing potential is pregnant at the time of institution of therapy should be considered. A negative result for pregnancy test having a sensitivity down to at least 50 mIU/mL for human chorionic gonadotropin (hCG) should be obtained within 2 weeks prior to TAZORAC® therapy, which should begin during a normal menstrual period.

TAZORAC® is contraindicated in individuals who have shown hypersensitivity to any of its components.

WARNINGS:
Pregnancy Category X. See CONTRAINDICATIONS section. Women of child-bearing potential should be warned of the potential risk and use adequate birth-control measures when TAZORAC® is used. The possibility that a woman of childbearing potential is pregnant at the time of institution of therapy should be considered. A negative result for pregnancy test having a sensitivity down to at least 50 mIU/mL for hCG should be obtained within 2 weeks prior to TAZORAC® therapy, which should begin during a normal menstrual period.

PRECAUTIONS:
General: TAZORAC® should be applied only to the affected areas. For external use only. Avoid contact with eyes, eyelids, and mouth. If contact with eyes occurs, rinse thoroughly with

Retinoids should not be used on eczematous skin, as they may cause severe irritation.

Because of heightened burning susceptibility, exposure to sunlight (including sunlamps) should be avoided unless deemed medically necessary, and in such cases, exposure should be minimized during the use of TAZORAC®. Patients must be warned to use sunscreens (minimum SPF of 15) and protective clothing when using TAZORAC®. Patients with sunburn should be advised not to use TAZORAC® until fully recovered. Patients who may have considerable sun exposure due to their occupation and those patients with inherent sensitivity to sunlight should exercise particular caution when using TAZORAC® and ensure that the precautions outlined in the Information for Patients subsection are observed.

TAZORAC® should be administered with caution if the patient is also taking drugs known to be photosensitizers (e.g., thiazides, tetracyclines, fluoroquinolones, phenothiazines, sulfonamides) because of the increased possibility of augmented photosensitivity.

Some individuals may experience excessive pruritus, burning, skin redness or peeling. If these effects occur, the medication should either be discontinued until the integrity of the skin is restored, or the dosing should be adjusted to a level or interval the patient can tolerate.

Weather extremes, such as wind or cold, may be more irritating to patients using TAZORAC®.

Information for Patients: See attached Patient Package Insert.

Drug Interactions: Concomitant dermatologic medications and cosmetics that have a strong drying effect should be avoided. It is also advisable to "rest" a patient's skin until the effects of such preparations subside before use of TAZORAC® is begun.

Carcinogenesis, mutagenesis, impairment of fertility:
A 2-year study of tazarotene following **oral** administration of 0.025, 0.050, and 0.125 mg/kg/day to rats showed no indications of increased carcinogenic risks. In this study, the mean Cmax of tazarotenic acid from the 0.125 mg/kg/day treatment group was 2.96 ng/mL, approximately one half of that in topically treated psoriatic patients extrapolated for treatment of 20% of body surface area with tazarotene cream.

An 88-week study following topical tazarotene gel application in mice at dose levels of 0.05, 0.125, 0.25 and 1.0 mg/kg/day (reduced to 0.5 mg/kg/day for males after 41 weeks due to severe dermal irritation) revealed no apparent carcinogenic effects when compared to vehicle control animals; untreated control animals were not completely evaluated. The Cmax and AUC values were 36 ng/mL and 136 ng·hr/mL for male mice at 1.0/0.5 mg/kg/day and 36 ng/mL and 239 ng·hr/mL for female mice at 1.0 mg/kg/day, respectively. The Cmax and AUC values for psoriatic patients treated with tazarotene cream under exaggerated conditions were 6.04$\pm$1.09 ng/mL and 98.4$\pm$18.6 ng·hr/mL respectively, extrapolated for 20% total body surface area.

Tazarotene was found to be non-mutagenic in both the Ames/Salmonella and E. coli assays and did not produce structural chromosomal aberrations in a human lymphocyte assay. Tazarotene was also non-mutagenic in the CHO/HPRT mammalian cell forward gene mutation assay and was non-clastogenic in the *in vivo* mouse micronucleus test.

No impairment of fertility occurred in rats when male animals were treated for 70 days prior to mating and female animals were treated for 14 days prior to mating and continuing through gestation and lactation with topical doses of tazarotene **gel** of up to 0.125 mg/kg/day.

Reproductive capabilities of F1 animals, including F2 survival, development, and behavior were not affected by topical administration of tazarotene **gel** to female F0 parental rats from gestation day 16 through lactation day 20 at the maximum tolerated dose of 0.125 mg/kg/day.

Pregnancy: Teratogenic Effects: Pregnancy Category X:
See CONTRAINDICATIONS section. Women of child-bearing potential should use adequate birth-control measures when TAZORAC® is used. The possibility that a woman of childbearing potential is pregnant at the time of institution of therapy should be considered. A negative result for pregnancy test having a sensitivity down to at least 50 mIU/mL for hCG should be obtained within 2 weeks prior to TAZORAC® therapy, which should begin during a normal menstrual period.

Nursing mothers:
After single topical doses of ^{14}C-tazarotene gel to the skin of lactating rats, secretion of radioactivity was detected in milk, suggesting that there would be transfer of drug-related material to the offspring via milk. It is not known whether this drug is excreted in human milk. Caution should be exercised when tazarotene is administered to a nursing woman.

Pediatric Use:
The safety and efficacy of tazarotene have not been established in pediatric patients under the age of 12 years.

Geriatric Use: Of the total number of subjects in clinical studies of tazarotene cream, 120 were over the age of 65. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

ADVERSE REACTIONS:
The most frequent adverse events reported with TRADENAME™ 0.05% and 0.1% creams were limited to the skin. Those occurring in 10 to 23% of patients, in descending order, included pruritus, erythema, and burning. Events occurring in >1 to <10% of patients, in descending order, included irritation, desquamation, stinging, contact irritant dermatitis, dermatitis, eczema, worsening of psoriasis, skin pain, rash, hypertriglyceridemia, dry skin, skin inflammation, and peripheral edema.

Tazarotene cream 0.1% was associated with a somewhat greater degree of local irritation than the 0.05% cream.

In human dermal safety studies, tazarotene 0.05% and 0.1% creams did not induce allergic contact sensitization, phototoxicity or photoallergy.

OVERDOSAGE:
Excessive topical use of TAZORAC® may lead to marked redness, peeling, or discomfort (see PRECAUTIONS).

TAZORAC® is not for oral use. Oral ingestion of the drug may lead to the same adverse effects as those associated with excessive oral intake of Vitamin A (hypervitaminosis A) or other retinoids. If oral ingestion occurs, the patient should be monitored, and appropriate supportive measures should be administered as necessary.

DOSAGE AND ADMINISTRATION:
Apply TAZORAC® cream once per day to psoriatic lesions, using enough ($2mg/cm^2$) to cover only the lesion with a thin film. If a bath or shower is taken prior to application, the skin should be dry before applying the cream. If emollients are used, they should be applied and allowed to absorb into the skin before application of TAZORAC®. Because unaffected skin may be more susceptible to irritation, application of TAZORAC® cream to these areas should be carefully avoided.

Application may cause excessive irritation in the skin of certain sensitive individuals. In cases where it has been necessary to temporarily discontinue therapy, or to reduce the frequency of application, therapy may be resumed or the frequency of application increased as the patient becomes able to tolerate the treatment. Frequency of application should be closely monitored by careful observation of the clinical therapeutic response and skin tolerance. Efficacy has not been established for less than once daily dosing frequencies.

HOW SUPPLIED:
TRADENAME™ is available in concentrations of 0.05% and 0.1%. It is available in a collapsible aluminum tube with a tamper-evident aluminum membrane over the opening and a white polypropylene screw cap, in 15g, 30g and 60g sizes.

	TAZORAC® Cream 0.05%	TAZORAC® Cream 0.1%
15 gm	NDC XXXX-XXXX-XX	NDC XXXX-XXXX-XX
30 gm	NDC XXXX-XXXX-XX	NDC XXXX-XXXX-XX
60 gm	NDC XXXX-XXXX-XX	NDC XXXX-XXXX-XX

Store at 0° – 35°C (32° - 95°F).
Excursions permitted from -5° – 40°C (23° - 104°F).

Rx only

ALLERGAN
Irvine, California 92612, USA September 1999 (PM#) (copy code)

Printed in USA

Pharmacist: Please cut or tear at dotted line and provide this patient package insert to your customer.

TAZORAC® ® ALLERGAN
(tazarotene topical cream) 0.05%
(tazarotene topical cream) 0.1%

INFORMATION FOR PATIENTS

Please read this leaflet carefully before you start to use your medicine. If you have any questions, or are not sure about anything, ask your doctor or pharmacist.

- The active ingredient in TAZORAC® is tazarotene.
- TAZORAC® cream also contains benzyl alcohol as a preservative and the following inactive ingredients: Carbomer 934P, carbomer 1342, edetate disodium, medium chain triglycerides, mineral oil, purified water, sodium thiosulfate, sorbitan monooleate and sodium hydroxide to adjust the pH.

USE

TAZORAC® 0.05% cream and TAZORAC® 0.1% cream are used in the treatment of plaque psoriasis.

BEFORE YOU USE THIS MEDICINE

You should be aware that:

(a) TAZORAC® should not be used if you are pregnant, attempting to become pregnant or at high risk of pregnancy. Consult your physician for adequate birth control measures if you are a female of child-bearing potential.

(b) TAZORAC® should be used with caution if you are also using other topical agents with a strong skin drying effect, products with high concentrations of alcohol, astringents, spices, the peel of lime, medicated soaps or shampoos, permanent wave solutions, electrolysis, hair depilatories or waxes, or other preparations or processes that might dry or irritate the skin, unless otherwise instructed by your health care practitioner.

(c) TAZORAC® should not be used if you have sunburn, eczema or other chronic skin condition(s). TAZORAC® may cause severe irritation if applied to eczematous skin. If you have sunburn, you should wait until full recovery before using TAZORAC®.

(d) TAZORAC® should not be used if you are inherently sensitive to sunlight.

(e) TAZORAC® should not be used if you are taking other drugs that increase your sensitivity to sunlight. Inform your physician if you are taking any other medications.

(f) You should use protective clothing and sunscreens with minimum SPF of 15 during the day when being treated with TAZORAC®. You should avoid direct sun exposure as much as possible and avoid sunlamps totally while being treated with TAZORAC®, unless advised otherwise by your doctor.

(g) If you have considerable sun exposure due to occupation, particular caution as described above should be exercised when using TAZORAC®.

(h) Weather extremes, such as wind or cold, may be more irritating to your skin while you are using TAZORAC®.

BEFORE YOU USE THIS MEDICINE

Tell your doctor:

(a) if you are pregnant or are considering becoming pregnant.
(b) if you are breast-feeding.
(c) if you are allergic to any ingredients in this medicine.
(d) if you are already using other products that make your skin dry.
(e) if you have a skin condition called eczema.
(f) if you will be subject to excessive sun exposure.
(g) if you are taking vitamin A supplements.

HOW TO USE THIS PRODUCT:

- Read the directions on your prescription label carefully. Ask your doctor or pharmacist to explain anything that you do not understand.
- If you become pregnant while using TAZORAC® you should immediately discontinue its use and contact your doctor.
- If you use a cream or lotion to soften or lubricate your skin, apply TAZORAC® after ensuring that there is no more of the first cream or lotion on the skin.
- With use of TAZORAC®, some people notice a feeling of itching, burning or stinging. This feeling may occur less often as your skin gets used to the medication. If irritation is excessive, consult your health care provider, who may adjust your medication temporarily to a more comfortable level. Effectiveness of this medication when used less often than once daily has not been proven.
- Do not cover treated areas with dressings or bandages.
- Never use more TAZORAC® than instructed and never use it more often than instructed, as application of larger amounts of medication than recommended will not lead to more rapid or better results, and marked redness, peeling or discomfort may occur.
- Wash your hands after applying the medication unless you are treating your hands for psoriasis. If the cream accidentally gets on areas you do not need to treat, wash it off.
- If TAZORAC® comes in contact with your eyes, wash your eyes with large amounts of cool water, and contact a doctor if eye irritation persists.

MISSED DOSES:

- If you forget or miss a dose of TAZORAC®, do not try to "make it up." Return to your normal application schedule as soon as you can.

INSTRUCTIONS SPECIFIC TO TREATMENT:

- If you bathe or shower before using TAZORAC®, be sure the skin is dry before application. Apply a thin film of the cream to your psoriasis lesions once a day.
- Carefully avoid application to apparently uninvolved skin. TAZORAC® may be more irritating to non-lesional skin.
- If you need to treat your hands, avoid contact with your eyes.
- Usually psoriasis plaques and scales will begin to improve in about one week, but the redness may take longer to improve. Continue to use TAZORAC® as directed by your doctor.
- Contact your doctor if your psoriasis becomes worse.

WARNINGS:
TAZORAC® should not be used if you are pregnant, attempting to become pregnant or at high risk of pregnancy. Women of child-bearing potential should use adequate birth-control measures when TAZORAC® is used.

If TAZORAC® is swallowed, contact your doctor or a poison control center.

Do not use TAZORAC® after the expiration date found on the bottom seal of the tube.

This medicine is for your use only. It can only be prescribed by a doctor. Never give it to anyone else. It may harm them even if their skin problem appears to be the same as yours.

Retinoids should not be used on eczematous skin, as they may cause severe irritation. Do not use TAZORAC® until your doctor has confirmed that your eczema has fully recovered.

Because of increased burning susceptibility, exposure to sunlight (including sunlamps) should be avoided or minimized during the use of TAZORAC®, unless prescribed differently by your doctor.

You should use sunscreens (minimum SPF of 15) and protective clothing when using TAZORAC®. Be certain that you use these precautions if you expect to experience considerable sun exposure or if you are sensitive to sunlight.

If you have a sunburn, do not use TAZORAC® until you have fully recovered.

Do not use TAZORAC® if you are also taking drugs known to be photosensitizers (e.g., thiazides, tetracyclines, fluoroquinolones, phenothiazines, sulfonamides), unless you have discussed taking both drugs with your doctor, because of the increased possibility of a more severe reaction.

INSTRUCTIONS FOR USE AND HANDLING: Keep tube tightly closed when not in use. Store it in a safe place where children cannot reach it. TAZORAC® Cream should be stored at 0° – 35°C (32° - 95°F): excursion permitted from -5° – 40°C (23° - 104°F).

IF YOU HAVE QUESTIONS ABOUT TAZORAC® CREAM: You may contact Allergan by calling 800-433-8871.

IF YOU HAVE QUESTIONS ABOUT PSORIASIS: Information is available from:
The National Psoriasis Foundation:
6600 SW 92nd Avenue, Suite 300, Portland, OR 97223-7195.
Telephone: (800) 723-9166, or on the World Wide Web at http://www.psoriasis.org.

ALLERGAN
Irvine, California 92612, USA September 1999 (PM#) (copy code)

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