

INFORMATION FOR THE CONSUMER

PrTAZORAC® Cream

Tazarotene 0.05% and 0.1% w/w

This leaflet is part of the "Product Monograph" published when TAZORAC® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about TAZORAC®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

TAZORAC® is a topical drug for the treatment of plaque psoriasis, acne and photodamage, to treat the signs and symptoms of premature aging due to overexposure to the sun such as the fine wrinkling, skin dryness, irregular or mottled pigmentation and liver spots on the skin.

What it does:

TAZORAC® is a preserved cream that contains tazarotene as the active ingredient which is a retinoid. The exact mechanism of action is not known. It is thought to act by helping skin cells to grow normally as well as having an anti-inflammatory effect in psoriasis and acne.

When it should not be used:

TAZORAC® must not be used by women who are or may become pregnant. If you become pregnant during TAZORAC® treatment, stop using TAZORAC® and contact your doctor immediately.

Do not use TAZORAC® if you have a skin condition called seborrheic dermatitis, a red, itchy, flaky, scaly inflammation of the skin.

Do not use TAZORAC® if you are allergic to tazarotene, retinoid compounds or any of the non-medicinal ingredients (see "What the important nonmedicinal ingredients are" section).

What the medicinal ingredient is:

Tazarotene

What the important nonmedicinal ingredients are:

Benzyl alcohol 1.0% (w/w) as a preservative, carbomer 934P, carbomer 1342, edetate disodium, medium chain triglycerides, mineral oil, purified water, sodium thiosulphate, sorbitan monooleate, and sodium hydroxide to adjust the pH

What dosage forms it comes in:

Cream, 0.05% and 0.1% w/w

WARNINGS AND PRECAUTIONS

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

BEFORE you use TAZORAC® talk to your doctor or pharmacist:

- if you are pregnant or plan to become pregnant while using this drug
- if you are breast feeding or planning to breast feed
- if you are already using other skin products that make your skin dry (see INTERACTIONS WITH THIS MEDICATION)
- if you have recently undergone a skin procedure such as skin peeling, dermabrasion or other similar procedure, allow your skin to heal before starting TAZORAC®
- if you have a skin condition called eczema. TAZORAC® may cause severe irritation if applied to eczematous skin
- if you are sensitive to sunlight

Other warnings:

- Avoid contact with the eyes and mucous membranes, eyes, lips and nose. In case of accidental contact, rinse thoroughly with large amounts of water.
- TAZORAC® may cause skin irritation, burning or itching. Contact your doctor if these effects become troublesome

Pregnancy:

- This product may harm the fetus. There are rare reports of birth defects in babies born to women who have used topical retinoids during pregnancy, but retinoids have not been proven as a cause. Avoid pregnancy during TAZORAC® treatment.
- Use adequate birth control measures during treatment. Your doctor may request a pregnancy test in the 2 week period before TAZORAC® treatment. (see Warnings, Use in Pregnancy section of the Product Monograph)
- If you become pregnant while using TAZORAC®, stop treatment immediately and contact your doctor.

Avoid excessive sun exposure, including sun lamps, as you may have a greater risk of sunburn during TAZORAC® treatment. Wear sunscreens SPF 15 or greater and protective clothing. If you get a sunburn, wait until full recovery before using TAZORAC®.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor about all the medications you are taking, including those without a prescription.

Medication that may interact with **TAZORAC**[®] include:

- medications that are applied to the skin and cosmetics that have a strong drying effect such as those containing alcohol, astringents, spices, lime peel, medicated soaps or shampoos, permanent wave solution, electrolysis, hair depilatories or waxes, or other products or processes that may dry or irritate the skin. Your doctor may tell you to stop using these products and allow your skin to heal before starting **TAZORAC**[®] treatment.
- medications that make you sensitive to the sun (e.g. thiazides (diuretics), antibiotics (tetracyclines, fluoroquinolones), phenothiazines, and sulfonamides)). Your doctor may advise that these medications should not be used during **TAZORAC**[®] treatment.

PROPER USE OF THIS MEDICATION

For external use only.

For all uses:

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 to help prevent skin irritation.

Psoriasis:

Usual adult dose and dose for children above the age of 12:

If you bathe or shower, be sure the skin is dry before applying **TAZORAC**[®]. Apply a thin film of the cream to your psoriasis lesions once a day before going to bed.

If you use a cream or lotion to soften or moisten your skin, apply emollients first, at least 1 hour before **TAZORAC**[®]. Apply **TAZORAC**[®] only after ensuring that the first cream or lotion has absorbed into the skin.

Avoid application to normal skin. **TAZORAC**[®] is sometimes more irritating to normal skin.

You may notice an improvement in your psoriasis as early as one week after starting **TAZORAC**[®] treatment. Continue to use **TAZORAC**[®] as directed by your doctor. Contact your doctor if your psoriasis becomes worse.

Acne:

Usual adult dose and dose for children above the age of 12:

Clean your skin gently. After it is dry, apply **TAZORAC**[®] 0.1% once a day in the evening to the affected areas. Use enough cream to cover the entire affected area with a thin film.

Follow your doctor's directions for other routine skin care and the use of make-up. Talk to your doctor about the use of cosmetics, especially those that dry your skin.

Your acne may begin to improve as early as 4 weeks after starting **TAZORAC**[®] treatment. Continue to use **TAZORAC**[®] as directed by your doctor.

Contact your doctor if your acne becomes worse.

Photodamage – The signs and symptoms of premature aging due to overexposure to the sun:

Usual adult dose and dose for children above the age of 12:

Remove makeup (if present) before applying **TAZORAC**[®]. If you wash your face prior to applying **TAZORAC**[®], you should allow your skin to dry first. Apply a pea-sized amount to lightly cover the entire face. Apply with special care around eyelids if desired. Do not spot treat. **TAZORAC**[®] should be applied once per day.

When treating the eyelid, wrinkles around the eye (Crow's feet) and mouth, special care must be taken to minimize contact with the eyes, lips and mucous-producing areas.

Follow your doctor's directions for other routine skin care and the use of make-up. It is recommended to use a sunscreen with an SPF of at least 15 during the day, but you should talk to your doctor about the use of sunscreens, moisturizers, and cosmetics. In general, facial moisturizers may be used as frequently as desired. If emollients or moisturizers are used, they can be applied either before or after tazarotene cream, but whichever one is applied first should be allowed to absorb into the skin before the next one is applied.

Although results will vary, you may begin to see improvement in about 2 weeks for mottled pigmentation, 8 weeks for fine wrinkling and varying times for other signs and symptoms. Continue to use **TAZORAC**[®] as directed by your doctor. Contact your doctor if your photodamage becomes worse.

General directions for use:

Your doctor may have told you to use **TAZORAC**[®] in a different way to that recommended in this leaflet. If so, follow your doctor's instructions about when and how to use the cream. Read the directions on your prescription label carefully. Ask your doctor or pharmacist to explain anything that you do not understand.

Remove the cap and check that the seal is not broken before you first use the cream. To break the seal, use the back of the cap.

Do not cover treatment areas with dressings or bandages. Excessive use of **TAZORAC**[®] will not provide faster or better results, and severe irritation or discomfort could occur.

TAZORAC[®] was prescribed by your doctor to treat your specific medical problem and is for your use only. Do not share it with others. It may harm them even if their skin problem appears to be the same as yours.

Overdose:

In case of oral ingestion or drug overdose, contact your doctor, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget a dose of TAZORAC®, do not try to make it up, simply return to your normal application schedule as soon as you can.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

| | |
|-------------|--|
| Very common | Occurs in more than 1 out of 10 patients |
| Common | Occurs in between 1 and 10 out of every 100 patients |

Like all medicines, TAZORAC® can have side effects. Most of the side effects are not serious. If these persist or cause you concern, consult your doctor.

Psoriasis:

Very common

- Burning and redness of the skin
- Itchy and irritated skin

Common

- Inflammation and pain of the skin
- Peeling of the skin
- Worsening of psoriasis
- Eczema
- Rash
- Stinging sensation of the skin

Acne:

Very common

- Burning, peeling and redness of the skin
- Dry skin

Common

- Itchy and irritated skin
- Stinging

Photodamage:

Very common

- Burning, peeling and redness of the skin
- Dry skin
- Inflammation of the skin

Common

- Itchy and irritated skin
- Stinging sensation of the skin
- Acne
- Rash

This is not a complete list of side effects. For any unexpected effects while taking TAZORAC®, contact your doctor or pharmacist.

HOW TO STORE IT

TAZORAC® should be stored at room temperature (15 - 25°C).

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

Keep the tube tightly closed when not in use. Store it in a safe place where children cannot reach it or see it.

Reporting Side Effects

You can help improve the safe use of health products for Canadians reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect;
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form

and sending it by:

- Fax to 1-866-678-6789 (toll-free), or
- Mail to:

Canada Vigilance Program
Health Canada, Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained by contacting the sponsor, Allergan Inc, at: 1-800-668-6424

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