

INFORMATION FOR THE CONSUMER

Pr TAZORAC® Gel

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 and acne. It is applied to the skin.

What it does:

TAZORAC® is a preserved gel that contains tazarotene as the active ingredient which is a retinoid. The exact mechanisms of action for psoriasis and acne are 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® should not be used by women who are or may become pregnant. If this drug is used during pregnancy, treatment should be stopped and discussed with your doctor.

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 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; ascorbic acid, butylated hydroxyanisole, butylated hydroxytoluene as antioxidants; carbomer 934P, edetate disodium, hexylene glycol, purified water, poloxamer 407, polyethylene glycol 400, polysorbate 40, and tromethamine

What dosage forms it comes in:

Gel, 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 products that make your skin dry (see INTERACTIONS WITH THIS MEDICATION)
- if you have a skin condition called eczema. TAZORAC® may cause severe irritation if applied to eczematous skin

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. 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 exposure to sun, 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 you heal before using TAZORAC®.

INTERACTIONS WITH THIS MEDICATION

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

Medications that may interact with TAZORAC® include:

- medications that are applied to the skin and cosmetics that have a strong drying effect. It is also advisable to "rest" a patient's skin until the effects of such preparations subside before use of TAZORAC® begins.
- medications that make you sensitive to the sun (e.g. thiazides (diuretics), antibiotics (tetracyclines, fluoroquinolones), sulfonamides)).

PROPER USE OF THIS MEDICATION

For external use only.

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 gel to your psoriasis lesions once a day before going to bed.

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

If you need to treat your hands, avoid contact with your eyes. Usually, you will notice an improvement in your psoriasis after about one week. 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®** once a day, before going to bed, to the areas where you have acne lesions. Use enough gel 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.

Usually, your acne will begin to improve in about 4 weeks. Continue to use **TAZORAC®** as directed by your doctor.

Contact your doctor if your acne 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 gel. Read the directions on your prescription label carefully. Ask your doctor or pharmacist to explain anything that you do not understand.

If you use a cream or lotion to lubricate your skin, apply it to your skin before applying **TAZORAC®**.

Remove the cap and check that the seal is not broken before you first use the gel. 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.

Wash your hands after applying the medication unless you are treating your hands for psoriasis. If the gel accidentally gets on areas you do not need to treat, wash it off.

This medicine was prescribed 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
- Skin pain
- Worsening of psoriasis

Common

- Skin peeling
- Dry skin
- Skin swelling
- Rash
- Stinging sensation of the skin

Acne:

Very common

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

Common

- Irritation of the skin
- Stinging sensation of the skin

*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 by 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

This leaflet was prepared by Allergan Inc.

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