

# Shining a light on sunscreen

How to sort out the profusion of sun protection products on store shelves

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With brighter summer days upon us, it's a good time to review the basics of sun protection so that we can better educate our patients about minimizing their chances of developing skin cancer.

Sun safety involves three main strategies. The first two are relatively straightforward, although they can be a tough sell to younger patients:

- Avoid sun exposure between 10 am and 4 pm (if outdoors, seek shade or use a sun umbrella), and avoid the use of artificial tanning beds;
- Wear sun-protective clothing such as light coloured, wide-brimmed (three-inch) hats, tightly woven full-length trousers, long-sleeve shirts and ultraviolet-blocking sunglasses.

The third sun safety message—regular and liberal use of sunscreens—is the one with the most traction, particularly for youth. But this strategy is complicated by the confusing array of products on the market, and by controversies over potentially “toxic” sunscreen ingredients.

How to sort things out for patients? First, some basics on ultraviolet (UV) radiation, the single biggest risk factor for the development of skin cancer.

## The UV spectrum

Electromagnetic radiation in the form of sunlight strikes the earth's atmosphere in three main forms: infrared, visible and ultraviolet. Ultraviolet radiation is further subdivided into three types based on wavelength: UVA (315–400 nm), UVB (280–315 nm) and UVC (100–280 nm). UVA makes up 90% to 99% of all UV radiation that reaches the earth's surface, followed by UVB (1% to 10%). UVC is absorbed by the atmosphere and poses little risk.

Historically, scientists believed UVB (which causes burning) was the main cause of skin cancer; however, it is now clear that UVA (which causes skin aging) is implicated. In genetically predisposed individuals, both types of rays can induce DNA mutations that result in skin cancer.



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**Regular sunscreen application is a key sun safety message, but the strategy is complicated by a confusing array of products.**

## Chemical and physical

Sunscreens act by absorbing, reflecting or scattering UV radiation. The two main categories are chemical sunscreens, which penetrate the superficial layers of the skin, and physical sunscreens, which coat the surface of the skin. Chemical sunscreens contain organic compounds that absorb UV radiation and convert it to heat, while physical sunscreens contain inert inorganic substances that block UV radiation by reflecting or scattering it. (Note that the term sunblock, used interchangeably with sunscreen in the past, is no longer considered acceptable under current labelling regulations.)

In general, sunscreens that are broad-spectrum with coverage for both UVA and UVB are most desirable. In Canada, sunscreens that contain zinc oxide or titanium dioxide (physical blockers) are categorized as natural health products and offer good broad-spectrum coverage. Chemical sunscreens are classified as drugs and contain at least one ingredient from Table 2 on the Health Canada web page at [tinyurl.com/chemicalsunscreens](http://tinyurl.com/chemicalsunscreens). The table also shows which ingredients are considered broad-spectrum. Most chemical sunscreens offer combinations of these ingredients for broader-spectrum coverage, under trademarked names such as Mexoryl XL (dometrisole trisiloxane) or

Helioplex (diethylhexyl 2, 6-naphthalate, avobenzone and oxybenzone). Many products combine chemical and physical ingredients.

## Sun protection factor

Prominently displayed on any sunscreen label is the sun protection factor (SPF), which was developed as a laboratory measure of effectiveness. The SPF represents the length of time that protected skin can be exposed to UVB before developing minimal erythema, compared with the time it takes for non-protected skin. This assumes the exposure intensity is constant, which it rarely is in practice. SPF gives us a gross indication of how much longer we could expect to be exposed to the sun before burning, compared with no sunscreen.

Generally, the higher the SPF the better the protection, but this relationship is not linear. SPF 60 does not offer double the protection of SPF 30. In fact, SPF 15 offers 93% protection while SPF 30 offers 96.7% and SPF 60 offers 97.7%. Additional protection beyond SPF 60 is marginal and may even give patients a false sense of security.

SPF only measures protection against UVB and does not measure UVA protection. Because we know UVA rays are also harmful, an SPF value is not an entirely accurate measure for overall skin protection. A sunscreen may have a high SPF

but offer little UVA protection. Measures for UVA protection are currently lacking in Canada.

In the United States, companies have taken advantage of the consumer's appetite for the highest-number sunscreen with products boasting 80,

90 and 100 SPF. However, last year the U.S. Food and Drug Administration introduced new labelling regulations that take effect on June 18 to simplify the sometimes exaggerated nomenclature used in marketing these products. Among other

TACTUO™ (adapalene/benzoyl peroxide) Topical Gel is indicated for the treatment of *acne vulgaris*, characterized by comedones, inflammatory papules/pustules with or without occasional nodules in patients 12 years of age and older. TACTUO™ is contraindicated in patients who are hypersensitive to adapalene, benzoyl peroxide or to any ingredient in the formulation or component of the container; patients with eczema or seborrheic dermatitis.

**For external use only. Not for ophthalmic use.**

Avoid contact with the eyes, lips, angles of the nose, mucous membranes, abraded skin and open wounds. If contact occurs, rinse thoroughly with water. Concomitant topical acne therapy is not recommended because a possible cumulative irritancy effect may occur, especially with the use of peeling, desquamating, or abrasive agents. Avoid concomitant use of other potentially irritating topical products (medicated or abrasive soaps and cleansers, soaps and cosmetics that have strong skin-drying effect and products with high concentrations of alcohol, astringents, spices, or limes).

Certain cutaneous signs and symptoms such as erythema, dryness, scaling, burning or pruritus are associated with the topical application of retinoids and can also be expected with the use of TACTUO™. These treatment-related effects generally occur during the first four weeks of therapy, are mostly mild to moderate in intensity, and usually lessen as the skin adjusts with continued use. Depending on the degree of the side effects, patients can be directed to use a moisturizer, use the medication less frequently or temporarily discontinue use until the symptoms subside.

As with any retinoid, exposure to excessive sunlight, including sunlamps, should be avoided while using the preparation, or a suitably effective sunscreen product and protective clothing over the treated areas is recommended when exposure cannot be avoided. Weather extremes, such as wind or cold, may also be irritating to patients under treatment with adapalene.

**It is recommended that topical adapalene/benzoyl peroxide should not be used by pregnant women. Topical adapalene/benzoyl peroxide should be used by women of childbearing years only after contraceptive counselling.**

It is not known whether adapalene or benzoyl peroxide is excreted in human milk following use of TACTUO™. Because many drugs are excreted in human milk, caution should be exercised when TACTUO™ is administered to a nursing mother. If applied to the chest, facial contact and oral ingestion by the infant from maternal skin may occur. No specific monitoring or hazards are associated with the use of the product in pediatric patients between the ages of 12 and 16 years. Safety and effectiveness of TACTUO™ in children below the age of 12 years have not been established. Safety and effectiveness of TACTUO™ in geriatric patients age 65 years and above have not been established.

The most frequently reported adverse reactions in two twelve-week clinical trials using TACTUO™ were: dry skin (6.9%), contact dermatitis (2.8%), application site burning (2.3%), application site irritation (1.4%) and skin irritation (1.1%).

In patients 12 years of age and older, TACTUO™ should be applied to affected areas of the face, chest and back once daily in the evening, after washing gently with a non-medicated cleanser. A small amount should be applied to provide a thin film, avoiding eyes, lips and mucous membranes. This medication should not be applied to cuts, abrasions, eczematous, or sunburned skin.

†A total of 517 subjects were randomized (2:2:2:1) in a double-blind, multi-center, controlled (active and vehicle) trial to receive either TACTUO™ (149), adapalene (148), benzoyl peroxide (BPO; 149), or vehicle (71) for 12 weeks.

‡A multi-center, open-label, single-arm study of 452 patients with *acne vulgaris*. Subjects applied once-daily TACTUO™ to the face for up to 52 weeks. Safety and efficacy evaluations were performed at baseline, week 1, week 2 and at months 1, 2, 4, 6, 8, 10 and 12.

References:

1. TACTUO™ Product Monograph, Galderma Canada Inc., March 18, 2011.
2. Thiboutot DM, et al. Adapalene-benzoyl peroxide, a fixed-dose combination for the treatment of *acne vulgaris*: Results of a multicenter, randomized double-blind, controlled study. *J Am Acad Dermatol*. 2007;57(5):791-799.
3. Pariser DM, Westmoreland P, Morris A, et al. Long-term safety and efficacy of a unique fixed dose combination gel of adapalene 0.1% and benzoyl peroxide 2.5% for the treatment of *acne vulgaris*. *Journal of Drugs in Dermatology*. 2007;6(9):899-905.



TACTUO™ is a trademark of Galderma Canada Inc.  
Galderma Canada Inc. Thornhill, Ontario



changes, the terms sunblock or waterproof will no longer be used, 50 will be the upper limit of advertisable SPF, and clearer definitions of skin cancer risk and “broad-spectrum” will be introduced. Importantly, sunscreens that claim to provide UVA protection will be required to pass a standardized test. In Canada, sunscreen labelling is regulated by Health Canada and is being updated.

In general, SPF 30 is regarded as a good, all-purpose sunscreen for active people who spend extended time outdoors. But more important than the SPF

is applying the correct amount of sunscreen. Most of us apply only 25% of that. A full ounce or 30 mL (the equivalent of a shot glass) is required to cover an exposed adult body. Sunscreen needs to be applied 20 minutes before the exposure to optimize skin absorption and then reapplied every two hours, preferably on non-sweaty skin.

#### Sunscreen safety

Controversy surrounding the risks of sunscreen ingredients is not new. For years, para-amino benzoic acid (PABA) was a staple constituent of sunscreens

products, acting as a chemical UVB absorber. In recent years, sunscreens containing PABA have largely fallen out of favour, not for any carcinogenic risk but due to their allergic potential. Many products now market themselves as being PABA-free.

The Environmental Working Group, a non-profit organization based in Washington, D.C., has sounded alarms about the safety of many commonly used sunscreen ingredients. For example, their 2011 report outlined concerns surrounding the chemical oxybenzone with respect to systemic absorption

and hormone disruptions as well as potential carcinogenicity from the non-active sunscreen ingredient retinyl palmitate. However, Health Canada and the American Academy of Dermatology have stated that available published evidence fails to substantiate these assertions. In Canada, sunscreen manufacturers are required to have authorization from Health Canada, demonstrating that their products are safe and effective, prior to sale. Nevertheless, ongoing safety evaluations of existing sunscreen ingredients should be an inte-

gral part of any Health Canada policy moving forward.

The vehicle in which the sunscreen is included plays a vital role in ensuring efficacy and preventing toxicity. Sunscreens come in creams, gels, lotions, ointments, sprays, lip balms and sticks. There are also waterproof formulations. The formulation really tends to be a personal choice based on personal need. A cream may be good for the face and body, whereas a gel may be good for hairy areas. Caution should be employed for all products, particularly sprays, used on the face and around eyes as they can be very irritating. There is no conclusive evidence that one vehicle works better than another.

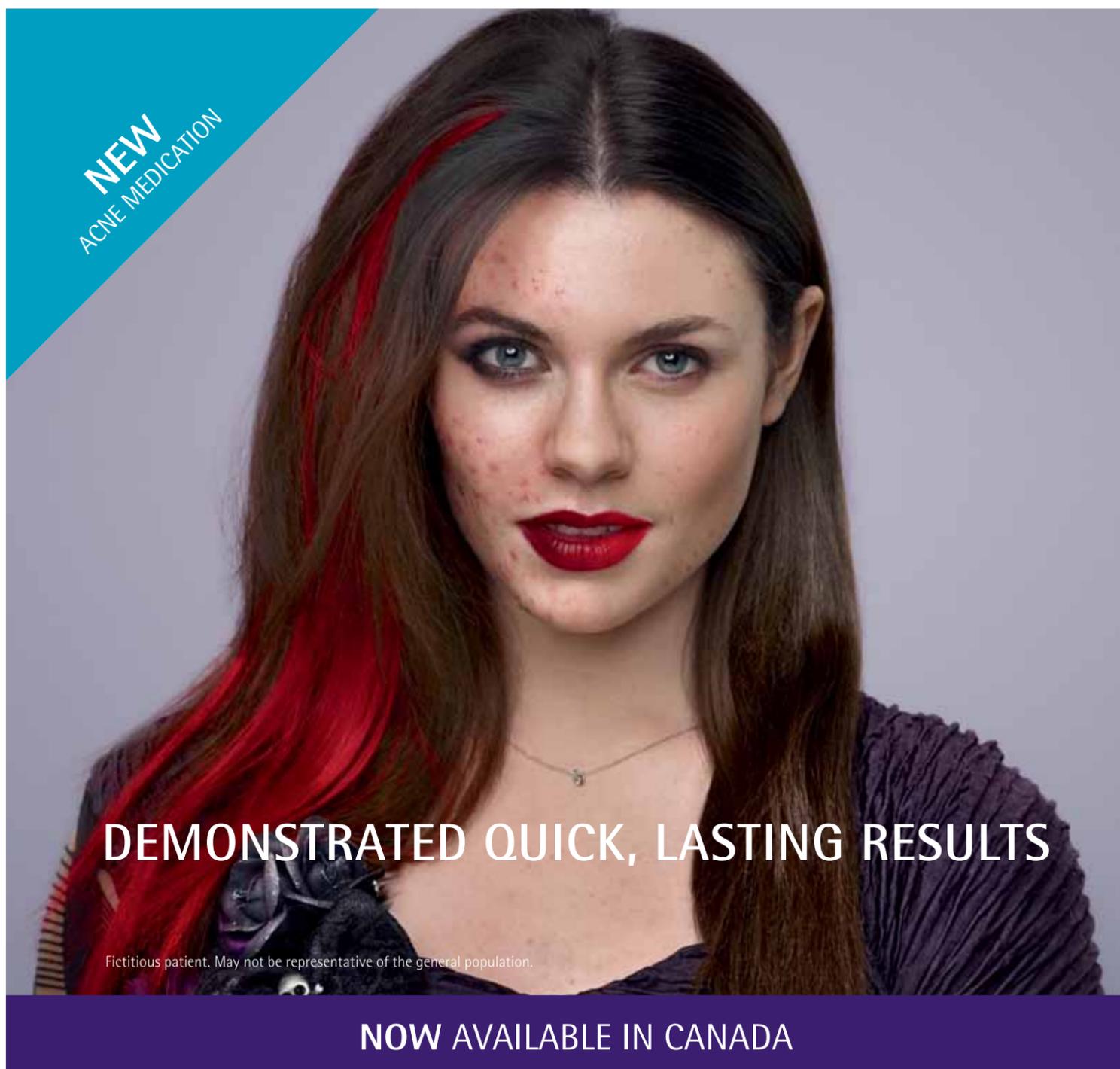
#### Age and ethnicity

Children younger than six months should be protected from direct sun exposure as their skin is thin and can burn, overheat and dehydrate easily. Sunburns in babies can be medical emergencies. The use of sunscreens should be avoided in this group as absorption, metabolic elimination and the risks and benefits of their use are still unclear. Beyond six months of age, the regular use of sunscreen is recommended for infants, toddlers and children.

In general, physical products are probably better for children, and even adults. The problem is they are often not esthetically pleasing. Newer formulations use smaller inorganic particles, but may lose efficacy. Combinations of inorganic and organic ingredients work synergistically and seem to be the trend.

Coloured skin is not immune to skin cancer and given Canada's multicultural patient population, the sunscreen discussion is highly germane. Individualizing sunscreen and sun exposure recommendations should be based on skin type and medical history.

Given that skin cancer rates continue to rise in Canada—with melanoma incidence increasing by 1.4% per year, for an estimated 5,500 cases and 950 deaths in 2011, according to the Canadian Cancer Society—sunscreen will remain a mainstay of sun-safety messaging. New products with optimized broad-spectrum protection, improved Canadian labelling standards and enhanced public education campaigns will proactively promote sun safety and help to keep our patients' skin cancer-free. **MP**



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✓ Mean percent reduction from baseline was **64% or greater** for all lesion counts at Week 52

✓ Inflammatory (66.4%), non-inflammatory (64.6%) and total lesion counts (65.1%)



See prescribing summary on page p8