CERAVE® HEALING OINTMENT: AN OTC OPTION TO CONSIDER

Barrier Support and Moisturizing Properties for a Range of Common Skin Concerns

The following is based in part on a roundtable discussion featuring:

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here was a dismissive perception some years ago that the practice of dermatology could be reduced to a simple axiom: If it's wet, dry it; if it's dry, wet it. Thankfully, the practice of dermatology has always been more sophisticated than that, and in today's health-care environment, advanced options for caring for the skin are readily available. Nonetheless, that notion of "wetting" the skin may be relevant to much of our current approach for compromised skin. Increasingly, we recognize the importance of skin hydration and moisturization—whether the skin appears outwardly dry or not. Dermatologists frequently recommend the use of an appropriate moisturizer.

Thanks in large part to the burgeoning field of epidermal barrier science, dermatologists now understand how a well-formulated topical moisturizer can help to restore lost hydration to the skin and reinforce epidermal barrier function. Numerous options are available to patients, hence it is incumbent on the prescriber to be aware of the options and offer recommendations. An over-the-counter formulation, CeraVe® Healing Ointment (Valeant), is among the options for improving skin hydration and to protect and soothe dry, cracked, and chafed skin.

MOISTURIZING THE SKIN

A hallmark of a healthy epidermal barrier is the presence of physiologic lipids: free fatty acids, ceramides, and cholesterol. These lipids can be incorporated into topical formulations for application to the skin with the goal of replacing lost lipids within the stratum corneum (SC).

In the over-the-counter space, moisturizer formulations have attempted to capitalize on the science of barrier repair. However, the characteristics¹ and price of products can vary tremendously. The type and the concentration of "lipids" and other ingredients in the formulations can vary tremendously.

CeraVe® Healing Ointment is formulated with ceramides 1, 3, and 6-II to repair and restore the epidermal barrier. These are physiologic lipids associated with dry skin. It is believed that delivering physiologic lipids can support a healthy skin barrier better than replacement with non-physiologic lipids.²

CeraVe® Healing Ointment also contains humectants, occlusives, and emollients—ingredients with distinct but interrelated actions to hydrate the skin and support a healthy skin barrier.³

Humectants work to draw moisture into the SC.² In CeraVe® Healing Ointment, hyaluronic acid is used as a humectant to draw moisture from the ambient environment into the SC. Occlusives lay on the skin to

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help seal in moisture and reduce transepidermal water loss (TEWL). Petrolatum serves this purpose in CeraVe® Healing Ointment. The CeraVe® formulation contains 46.5% petrolatum, which is more than the proportion in the market-leading formulation. Emollients lay on the skin and help impart a smooth skin feel. Emollients, such as ozokerite and paraffin, along with dimethicone, contribute to the non-greasy feel of the CeraVe® Healing Ointment formulation on the skin.

The effects of CeraVe® Healing Ointment on skin barrier function were investigated in two recent studies.⁴ Results showed that CeraVe® Healing Ointment improved SC hydration and reduced TEWL for at least eight hours after a single application in normal skin. In the clinical trial, where the skin barrier was intentionally compromised, CeraVe® Healing Ointment improved hydration within four hours after application and maintained hydration up to 18 hours after application.

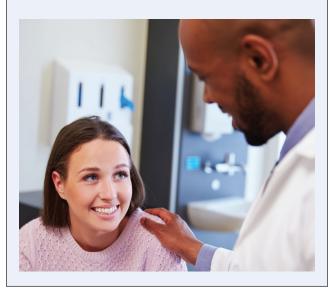
In the first study, 16 healthy females applied CeraVe® Healing Ointment one time to the skin of one volar forearm, and compared effects to untreated control. TEWL measurements were taken at both sites at 2, 4, 8, and 24-hours post application. Bathing was not permitted during the 24-hour study period or within one hour of the initial ointment application. Mean TEWL rates were significantly reduced for CeraVe® Healing Ointment, compared to untreated controls at 2, 4, and 8 hours.

In the second study, 39 male and female volunteers, ages 18 to 55, underwent a controlled shave procedure (a model of impaired skin barrier function) at baseline. Subjects were randomized to receive no treatment or to apply CeraVe® Healing Ointment twice daily for three

AN EVERYDAY MOISTURIZER IS VITAL TO THE CARE OF PATIENTS WITH DRY, COMPROMISED SKIN

Summary of Considerations When Recommending Moisturizers

- · Choose products that are accessible to patients.
- Ointments are especially beneficial for occlusive/ moisturizing properties.
- Non-irritating, hypoallergenic formulations are beneficial.
- Avoid ingredients associated with a higher risk of irritation or allergic reactions.
- Topically applied ceramides may help reinforce the epidermal barrier.



days, beginning the day after the shave procedure or Study Day 1. Skin moisture content was measured via skin conductance readings at baseline and through Day 4.

Within four hours of the first ointment application on Day 1, subjects using CeraVe® Healing Ointment had significantly higher mean conductance readings compared to controls. Mean conductance readings were significantly higher for the ointment arm through Day 4; the reading was taken 18 hours after the last ointment application.

FORMULATION IN FOCUS

An important consideration when recommending products is the "skin feel" of the product base. Some prescribers may prefer that patients use ointments because of their perceived moisturizing and occlusive properties, while some patients refuse ointments because they may leave a sticky, tacky, or greasy residue on the skin. Prescribers also may prefer petrolatum-based ointments because most do not require preservatives in the formulation, and they also tend to contain fewer ingredients, overall, than do many lotions or creams. As a result, ointments with few ingredients may introduce less potential to irritate skin.

CeraVe® Healing Ointment has no aqueous phase. Since it contains no water, it does not require preservatives. CeraVe® Healing Ointment is also free of fragrances, dyes, and lanolin—all of which are potential irritants or allergens. The prevalence of lanolin allergy is disputed, although reactions have been clearly documented. The ingredient is still widely used in many OTC formulations, but many prescribers avoid recommending formulations that contain lanolin.

The tolerability of CeraVe® Healing Ointment was confirmed in three recent studies, which found that the formulation is non-irritating, non-sensitizing, and non-comedogenic.⁶ In the first study, 106 male and female volunteers, ages 18-79, underwent application of CeraVe® Healing Ointment on the back, under occlusion, for 24 hours on Mondays, Wednesdays, and Fridays. After a two-week wash-out period, CeraVe® Healing Ointment was applied to virgin skin on the back under occlusion. No reactivity was observed at any time in any subject.

In the second study, 29 male and female volunteers, ages 18-62, had CeraVe® Healing Ointment or a negative control (water) applied to the back under occlusive patch for 24 hours. At the end of 24 hours, a fresh patch was applied daily for two weeks. Total mean and cumulative irritation scores for CeraVe® were zero—the same as for water.

In the third study, 17 male and female subjects with a history of acne, ages 25-55, had CeraVe® Healing Ointment under occlusive patch, acetylated lanolin under occlusive patch, or blank patch applied to the subjects' back for one week. No skin irritation was observed. Skin follicular biopsies showed the presence of microscopic microcomedones to be similar for CeraVe® Healing Ointment and blank patch and significantly lower for CeraVe® Healing Ointment, compared to acetylated lanolin.

Importantly, CeraVe® Healing Ointment has a nongreasy feel. Most patients will find it suitable for use at bedtime, though many will likely be willing to use it in "An important consideration when recommending products is the "skin feel" of the product base. Some prescribers may prefer that patients use ointments because of their perceived moisturizing and occlusive properties..."

the morning, as well. It is worth noting that some patient populations—particularly children—are used to greasy topical formulations and have fewer objections to ointments. They may be particularly pleased with the new refined ointment formulation.

PRACTICAL APPLICATIONS

A cosmetically acceptable healing ointment can be useful for a range of patients in the dermatology clinic. Applied immediately after a bath, a topical ointment can create a physical barrier to water evaporation that helps the skin retain hydration and supports healing. Use of an ointment may be recommended to help maintain healthy looking skin.

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