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Filing date: **04/27/2012**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	92052897
Party	Defendant Galderma Laboratories, Inc.
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Signature	/Lisa N. Congleton/
Date	04/27/2012
Attachments	Declaration of Cindy Kee Part 1.pdf (44 pages)(7399556 bytes)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Thomas Sköld Petitioner,	§	Cancellation No.: 92052897
v.	§	Mark: RESTORADERM
Galderma Laboratories, Inc. Registrant.	§	Reg. Nos.: 2,985,751 and 3,394,514

DECLARATION OF CINDY KEE
IN SUPPORT OF REGISTRANT'S MOTION FOR PARTIAL SUMMARY JUDGMENT

I, Cindy Kee, declare as follows:

1. I am Group Product Director, Cetaphil, of Galderma Laboratories, L.P. ("Galderma").

2. Galderma is a wholly, indirectly-owned operating entity of Registrant Galderma Laboratories, Inc. (collectively, "Registrant").

3. I have been with Galderma for over seventeen (17) years. I manage both the long-term branding strategy of Registrant's RESTORADERM brand and the day-to-day marketing activities in support of Registrant's RESTORADERM products.

4. I am over the age of eighteen (18) and am competent to make this declaration.

5. I have personal knowledge of the matters which are the subject of this declaration.

6. I am authorized by Registrant to make these statements and to execute this declaration.

7. Registrant currently offers two RESTORADERM-branded products in the United States for sale in retail stores nationwide: RESTORADERM Skin Restoring Body Wash and RESTORADERM Skin Restoring Moisturizer. Attached as Exhibits A - C are true and correct copies of examples of marketing materials Registrant currently uses to advertise and market the RESTORADERM products it currently offers. Specifically, Exhibit A comprises copies of Registrant's current website pages at *www.cetaphil.com* describing the RESTORADERM products and their properties and uses. Exhibit B comprises materials Registrant currently distributes or presents to dermatologists in the United States to educate dermatologists about Registrant's RESTORADERM products. Exhibit C comprises coupons

currently being distributed to U.S. consumers for use in purchasing Registrant's RESTORADERM products.

8. The RESTORADERM products were specifically designed to work together as a daily regimen to provide continuous relief for those struggling with atopic dermatitis and/or eczema-prone skin. *See* Exhibits A, B.

9. Registrant's RESTORADERM products feature clinically proven, advanced skin care technology, including:

- Filaggrin™ Breakdown Products – arginine and sodium-PCA, two ingredients with an affinity for, and ability to, trap water; and
- Patented ceramide technology – proprietary technology which works to trap water in the skin.

See Exhibits A, B.

10. Registrant's RESTORADERM Skin Restoring Body Wash is a foaming wash specially formulated to help skin retain moisture and maintain the skin barrier function. *See* Exhibits A, B.

11. Registrant's RESTORADERM Skin Restoring Moisturizer is specially formulated to restore moisture to atopic and/or eczema-prone skin and to help replenish, repair, and protect the skin's natural moisture barrier. *See* Exhibits A, B.

12. Both RESTORADERM products have been awarded the National Eczema Association's ("NEA") Seal of Acceptance, which is awarded to products that have been created or intended for use by persons with eczema or severe sensitive skin conditions and have satisfied certain other NEA Seal of Acceptance Criteria. *See* Exhibits A - C.

REDACTED

REDACTED

14. Following these clinical studies and assessments, Registrant decided upon formulations that achieved Registrant's product goals of offering skin care products for the treatment of atopic dermatitis that both increased skin hydration and restored skin barrier function. These formulations are the basis of the current RESTORADERM products.

REDACTED

REDACTED

By the end of July 2010, the RESTORADERM products were available in retail stores across the United States. *See* Exhibit E, slide no. 26.

19. Four of the studies discussed above completed on the RESTORADERM formulations formed the basis of an article published in the July 2011 issue of the peer-reviewed publication Journal of Drugs in Dermatology. A true and correct copy of that article, by Dr. Eric Simpson MD MCR and Yves Dutronc MD, entitled *A New Body Moisturizer Increases Skin Hydration and Improves Atopic Dermatitis Symptoms Among Children and Adults*, is attached as Exhibit L.

20. Registrant considers the RESTORADERM brand and business to be important and valuable assets.

REDACTED Registrant expends substantial resources in

protecting and promoting the brand. REDACTED

21. I declare, under penalty of perjury under the laws of the United States of America and 28 U.S.C. § 1746, that the foregoing is true and correct, and that this declaration was executed this 27th day of April 2012 in Fort Worth, Texas.

Cindy Kee

Declaration of Cindy Kee

EXHIBIT A

Cetaphil® RESTORADERM® *Skin Restoring Body Wash*

10 fl oz

Like 159 WHERE TO BUY

Relief for eczema-prone skin.
Cetaphil® RESTORADERM® Skin Restoring Body Wash* is suited for anyone three months of age and older. Developed as part of a daily regimen with Cetaphil® RESTORADERM® Skin Restoring Moisturizer to gently cleanse very dry, eczema-prone skin, this specially formulated body wash helps the skin retain moisture.

Using advanced-technology, this creamy wash gently cleanses and rinses without irritation and holds skin-nourishing oils in a gentle, soap-free cleanser to soothe the dry, itchy skin associated with atopic dermatitis.

Free of fragrances, parabens and nut oils, Cetaphil® RESTORADERM® Skin Restoring Body Wash is a gentle, non-irritating foaming cleanser that can help maintain the skin barrier function.

* Avoid contact with eyes when using RESTORADERM® Skin Restoring Body Wash.

The NEA has awarded the Seal of Acceptance to Cetaphil® RESTORADERM® Skin Restoring Body Wash. The National Eczema Association (NEA) Seal of Acceptance is awarded to products that have been created or intended for use by persons with eczema or severe sensitive skin conditions and have satisfied the NEA Seal of Acceptance Criteria. Read the label to determine if this product may contain ingredients that may be unsuitable for your skin.

REVIEWS CONSIDER USING WITH INGREDIENTS SPECIAL INSTRUCTIONS

Great Body Wash for Skin Problems
This is a great product if you have eczema, it is very mild, and helps keep the skin irritations down.
— judy (Ocala, Florida)

BEST STUFF EVER!!!!
This stuff is the best ever!!! I have tried everything out there under the sun! I am transformed into this soft glowy princess whenever I use this plus the lotion. While I know its a bit pricy, it is so worth it! Even my boyfriend says my skin is so pretty when I use this stuff. I have been a fan of this company for over thirteen years! Kudos to Cetaphil for another awesome product!
— mel (California)

READ MORE REVIEWS AT: DRUGSTORE.COM OR AMAZON.COM

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PUBLIC

Cetaphil® RESTORADERM® *Skin Restoring Moisturizer*

10 fl oz

Like 135 WHERE TO BUY

Long lasting moisture for eczema-prone skin.
Cetaphil® RESTORADERM® Skin Restoring Moisturizer is suited for anyone three months of age and older with dry, itchy skin symptoms commonly associated with eczema or atopic-dermatitis. Best used after cleansing with RESTORADERM® Skin Restoring Body Wash, this effective moisturizer with patented Filaggrin technology™ and ceramide technology is formulated to hydrate and soothe very dry, atopic skin.

Developed to help replenish and protect the skin's natural moisture barrier, this nourishing skin moisturizer offers gentle yet effective hydration for dry, itchy skin. Free of fragrances, parabens and nut oils, Cetaphil® RESTORADERM® Skin Restoring Moisturizer is easily absorbed and restores moisture to help repair the skin's barrier. Use as part of a dermatologist-recommended, daily skin care routine for the management of eczema.

The NEA has awarded the Seal of Acceptance to Cetaphil® RESTORADERM® Skin Restoring Moisturizer. The National Eczema Association (NEA) Seal of Acceptance is awarded to products that have been created or intended for use by persons with eczema or severe sensitive skin conditions and have satisfied the NEA Seal of Acceptance Criteria. Read the label to determine if this product may contain ingredients that may be unsuitable for your skin.

REVIEWS CONSIDER USING WITH INGREDIENTS SPECIAL INSTRUCTIONS

Excellent Product!
I have extremely dry, thin skin and nothing works as well as this for moisturizing my skin. It works well on face as well. It also seems like it has a cumulative effect perhaps - the more regularly I use it the better my skin is.
— mzj (Washington)

reorder forever
This has become the one and only moisturizing cream for me and my husband, as recommended by our dermatologist.
— tc (Whidbey Island, WA)

READ MORE REVIEWS AT: DRUGSTORE.COM OR AMAZON.COM

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Advanced skin care technology

Serious skin conditions require serious skin care products. Individuals suffering from eczema-prone or acne-prone skin may deal with their condition on a daily basis. That's why we offer Cetaphil® skin care systems. These daily regimens feature clinically proven advanced skin care technology formulated to address these stubborn skin conditions.

Learn more about managing itchy, irritated, eczema-prone skin »
Learn more about managing oily, shiny, acne-prone skin »

As with any serious skin condition, be sure to talk to your doctor before starting any new skin care regimen to find out what's best for you.

About eczema-prone skin

Itchy, irritated skin that doesn't properly retain moisture is a common symptom of eczema, a general term that refers to a family of skin conditions that causes the skin to become inflamed, swollen, irritated and itchy; atopic dermatitis is one of the most common types of eczema.

Cetaphil® RESTORADERM® Skin Restoring system for eczema-prone skin

Cetaphil® RESTORADERM® Skin Restoring Body Wash and Moisturizer were specifically designed to work together as a daily regimen to help those struggling with the itch and irritation associated with stubborn, eczema-prone skin — even in children as young as three months.

In people with eczema, research has discovered that filaggrin proteins may be missing or may not function correctly. This can lead to the disruption of the skin barrier so that even things like water, soaps, fragrances or dyes can cause people to experience eczema symptoms.

Cetaphil® RESTORADERM® Skin Restoring Body Wash and Moisturizer leverage patented Filaggrin technology™ and ceramide technology to combat the frustrating symptoms common with eczema-prone skin.

This advanced skin care system replenishes the skin's natural lipids, improving its ability to retain moisture and rebuild its damaged barrier. Used together as part of a daily skin care regimen, these products can soothe the itch, help reduce redness and dryness, and ease the irritation of eczema-prone or atopic skin. Both skin care products are clinically proven to be suitable for total-body use and are appropriate for ages three months and above.

About acne-prone skin

Acne can occur when your body produces too much oil. This can cause your pores to become plugged with both oil and dead skin cells. The pores become inflamed, causing pimples and blackheads.

Cetaphil® DERMACONTROL™ Oil Control system for acne-prone skin

Cetaphil® DERMACONTROL™ Oil Control Foam Wash and Moisturizer were specifically designed to work together as a daily regimen to help combat symptoms associated with acne. Formulated with dermatologists and clinically tested, this regimen is proven to cleanse, hydrate and protect skin.

Cetaphil® DERMACONTROL™ Foam Wash and Moisturizer are formulated with new zinc technology. And, thanks to our patented oleosome and ceramide technologies, this system provides daily sun protection while it helps replenish the skin's natural moisture barrier, leaving skin feeling refreshed and hydrated.

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When used together, these products cleanse skin, remove oil and restore skin's natural moisture balance – without over-drying or irritating skin. This cleansing and moisturizing skin care system balances control of both acne symptoms and some acne treatment effects. In fact, clinical testing has shown the DERMACONTROL™ system helps to reduce dryness and roughness in patients using prescription acne treatments.

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Declaration of Cindy Kee

EXHIBIT B

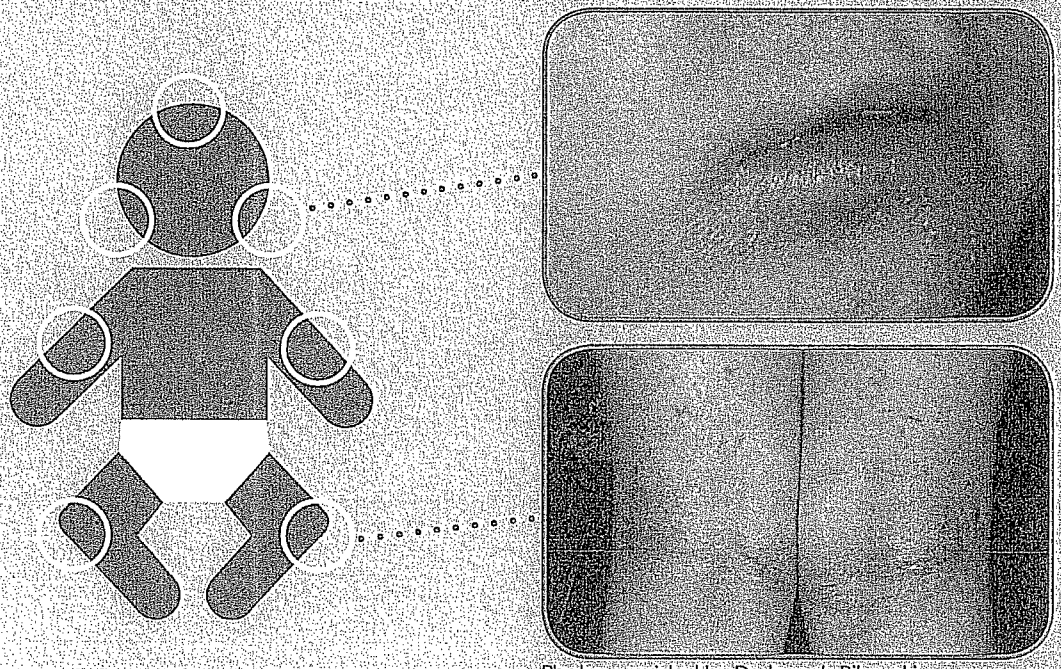
Atopic dermatitis: Deficiencies can lead to a compromised skin barrier

Filaggrin and ceramide deficiencies can occur in atopic dermatitis[1,2]

- These deficiencies can lead to a compromised skin barrier[1,2]
- Symptoms (dry, itchy rash) are the result of a compromised skin barrier[3]
  - —These symptoms can lead to sleeplessness and irritability

In children, atopic dermatitis can occur all over the body

Patches commonly appear on the scalp, face and in the bends of the joints (knees and elbows)[4]



Photos provided by Dr. Joseph Bikowski

Cetaphil® RestoraDerm® products: uniquely formulated to meet the needs of atopic dermatitis patients

Patented technologies help replenish the skin barrier

Filaggrin technology™ works to improve hydration, which helps restore skin barrier function[2,3,5]

Ceramide technology enhances the skin's natural ability to retain moisture[6]

Proven to significantly restore skin barrier function (compared with baseline) over 4 weeks

- Decreased transepidermal water loss (TEWL)[5]
- Increased hydration as assessed by corneometry[5]

Provides proven symptom relief for your patients

- Soothes the dry, itchy skin of eczema[5]
- Proven highly tolerable on atopic skin[5]

Cetaphil®
RESTORADERM®

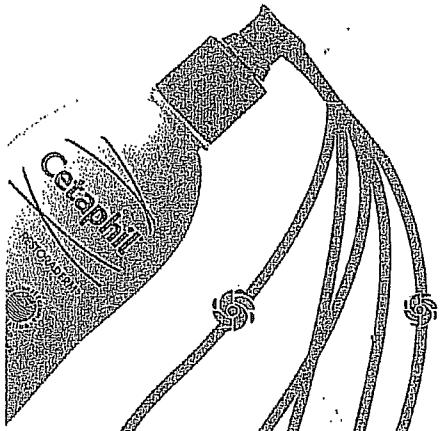
ATOPIC DERMATITIS: Results in skin barrier dysfunction

Filaggrin: A protein deficiency in atopic skin

~ Filaggrin deficiency compromises barrier function, leaving skin vulnerable to irritants and allergens[1]

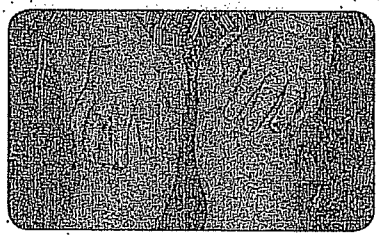
Ceramides: Lipid deficiency in atopic skin

~ Reduced levels of ceramides 1 and 3 cause excess water loss and a damaged skin barrier[1]



Cetaphil® RESTORADERM® Skin Restoring Moisturizer and Body Wash: The first and only products with ceramide AND Filaggrin technology™

- Filaggrin technology™ helps restore moisture to help rebuild the damaged skin barrier[1,2]
- Ceramide technology increases ceramides 1, 2 and 3[3]
- Cetaphil® RESTORADERM® Moisturizer is associated with increased levels of ceramides in atopic skin[2]



Soothes symptoms of eczema

~ Relieves dry, itchy skin[2]

~ Provides long-lasting hydration[2]

GALDERMA
Committed to the future of dermatology

PUBLIC

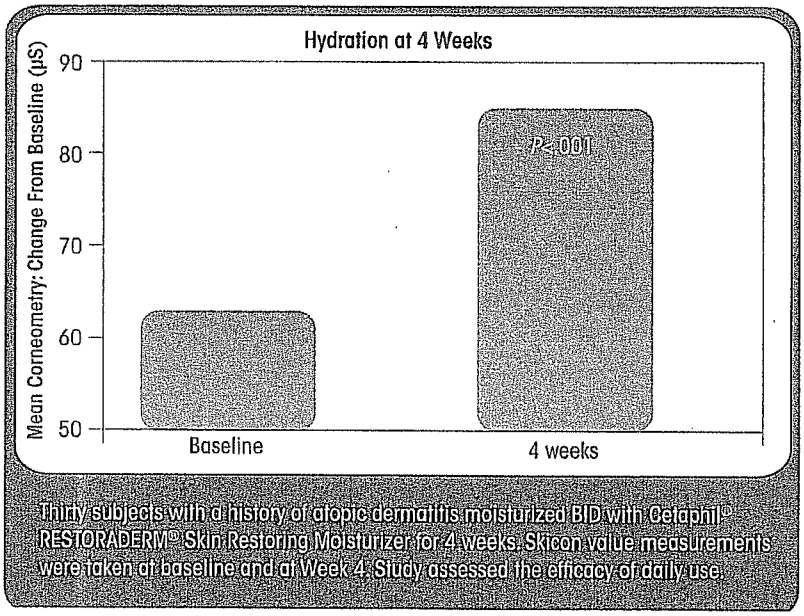
Proven results in atopic patients

Cetaphil® RESTORADERM® Skin Restoring Moisturizer

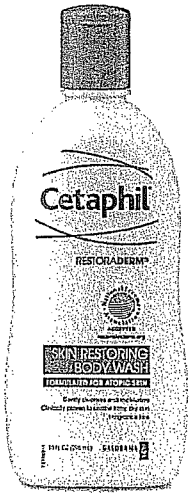
- Reduces and prevents dryness to help break the itch-scratch-itch cycle[2]
- Clinically proven to help restore skin barrier function[2]
- Provides long-lasting hydration for atopic skin[2]

Safe for use in children as young as 3 months[2]

Significantly increased hydration after 4 weeks[2]



Thirty subjects with a history of atopic dermatitis moisturized BID with Cetaphil® RESTORADERM® Skin Restoring Moisturizer for 4 weeks. Skicon value measurements were taken at baseline and at Week 4. Study assessed the efficacy of daily use.



Gentle enough to bathe atopic skin— Cetaphil® RESTORADERM® Skin Restoring Body Wash[2]

- Encapsulates skin-nourishing oils in a soap-free foaming wash[2]
- Helps soothe itch and reduces redness, dryness and irritation[2]
- Maintains skin barrier function and prevents transepidermal water loss[2]

PULL

Cetaphil® RESTORADERM® products are proven non-irritating on atopic skin[2]

- Contain no preservatives, fragrances, nut oils, parabens or lanolin[2]
- High patient satisfaction—up to 92% of patients reported they would continue using Cetaphil® RESTORADERM®[2]

National Eczema Association ACCEPTED nationaleczema.org

The National Eczema Association (NEA) Seal of Acceptance is awarded to products that have been created or intended for use by persons with eczema or severe sensitive skin conditions and have satisfied the NEA Seal of Acceptance Criteria. NEA has awarded the Seal of Acceptance to these products with a 4 out of 5 rating. Read the label to determine if these products contain ingredients that may be unsuitable for your skin. Visit nationaleczema.org for more information.

Cetaphil® RESTORADERM®

Replenish. Restore. Rebuild.

Complete formula for atopic skin[2]

	Formulated for Atopic Skin	Ceramides	Filaggrin Proteins	Niacinamide	Sunflower Seed Oil	Glycerin	Shea Butter
Cetaphil® RESTORADERM® Skin Restoring Moisturizer	✓	✓	✓	✓	✓	✓	✓
Cetaphil® RESTORADERM® Skin Restoring Body Wash	✓		✓	✓	✓	✓	✓
CeraVe® Body Moisturizers and Cleanser		✓				✓	
Eucerin® Calming Crème						✓	
Aveeno® Advanced Care		✓				✓	

Available at locations nationwide, including:

- CVS
- Duane Reade
- Rite Aid
- Walgreens
- Walmart

PULL

Look for Cetaphil® RESTORADERM® in the skin care aisle

- Average retail price: **$13.99-$14.99**
- Available in **10 fl oz bottles**

www.cetaphil.com

References: 1. Sugarman JL. The epidermal barrier in atopic dermatitis. *Semin Cutan Med Surg.* 2008;27:108-114. 2. Data on file. Galderma Laboratories.

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GALDERMA
mmitted to the future
of dermatology

Cetaphil® RESTORADERM®
Replenish. Restore. Rebuild.

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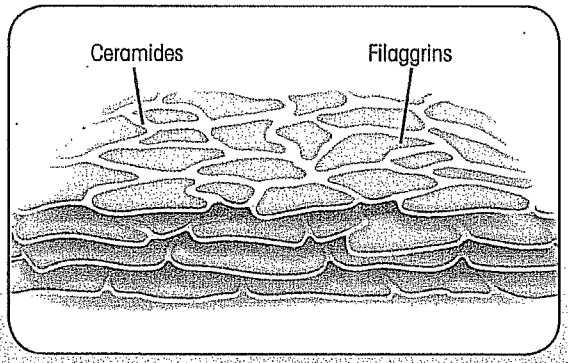
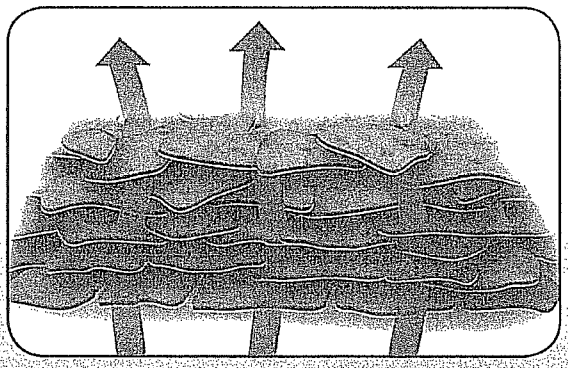
Atopic dermatitis: The result of a skin barrier dysfunction

HEALTHY SKIN

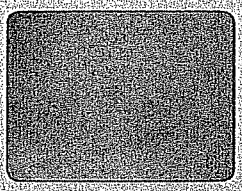


- Ceramides are lipids in the stratum corneum[1]
- Filaggrins are proteins in the stratum corneum[1]

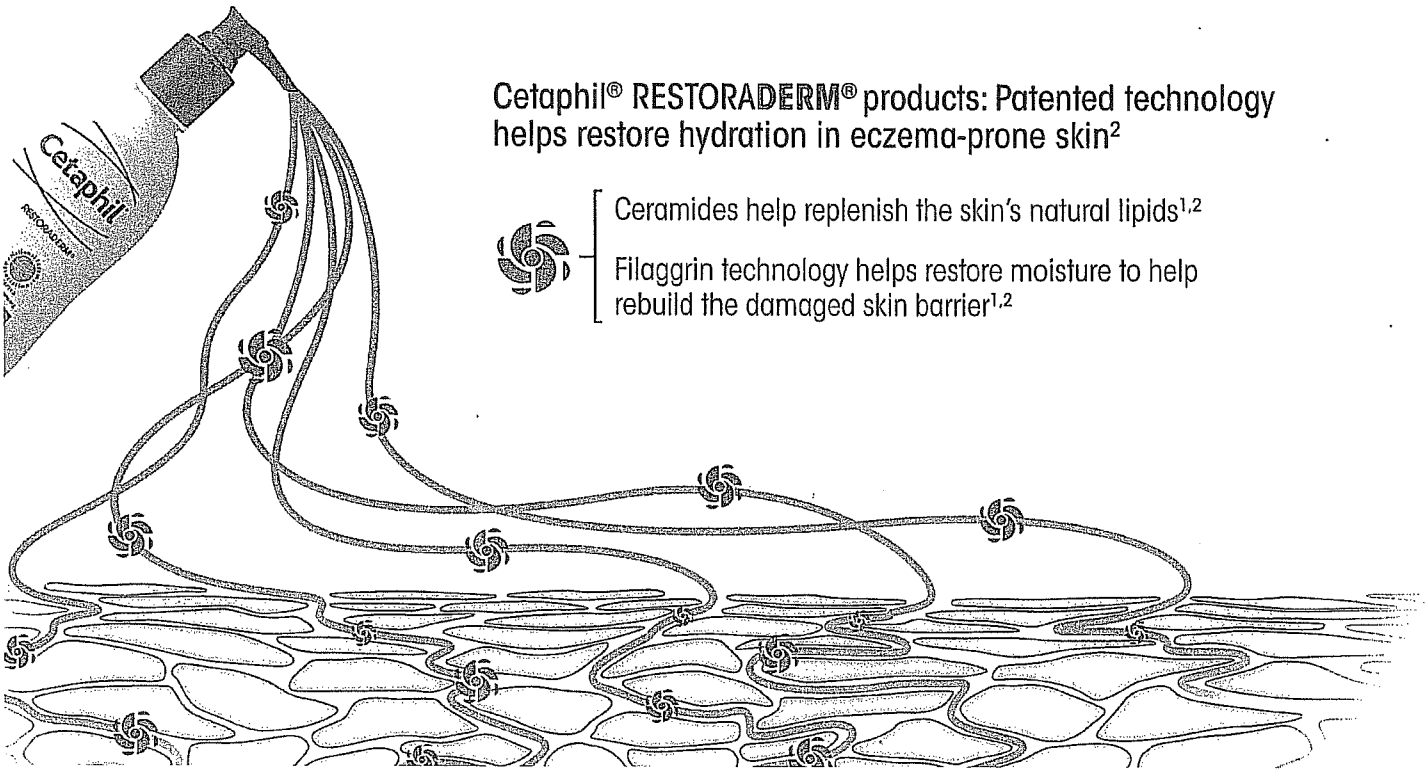
ATOPIC DERMATITIS—A FORM OF ECZEMA



- Reduced levels of ceramides result in damaged skin barrier and excessive water loss[1]
- Filaggrin deficiency compromises barrier function, leaving skin vulnerable to irritants and allergens[1]



Now replenish skin at the structural level



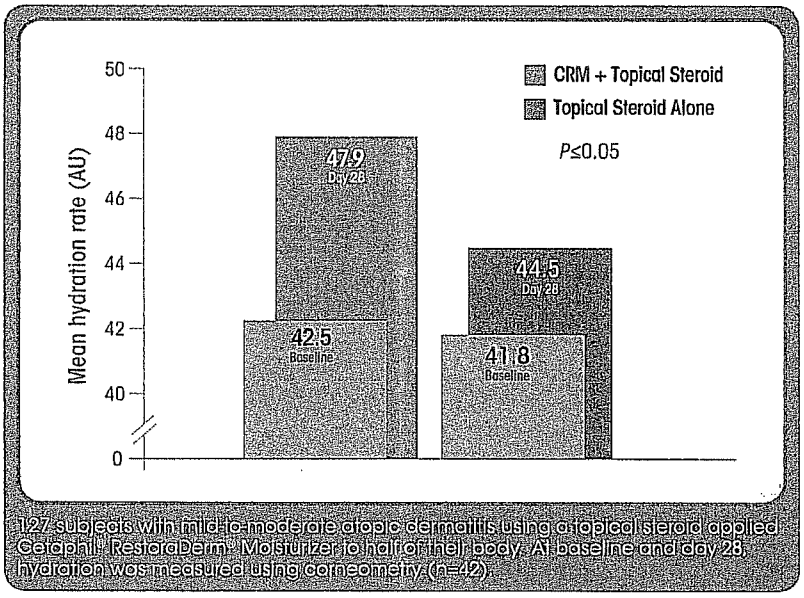
Cetaphil® RESTORADERM® products: Patented technology helps restore hydration in eczema-prone skin[2]

- Ceramides help replenish the skin's natural lipids[1,2]
- Filaggrin technology helps restore moisture to help rebuild the damaged skin barrier[1,2]

Improves hydration and decreases overall disease severity

Newly published data[3] for Cetaphil® RestoraDerm® Moisturizer

Significant hydration versus topical steroid treatment alone[3,5]

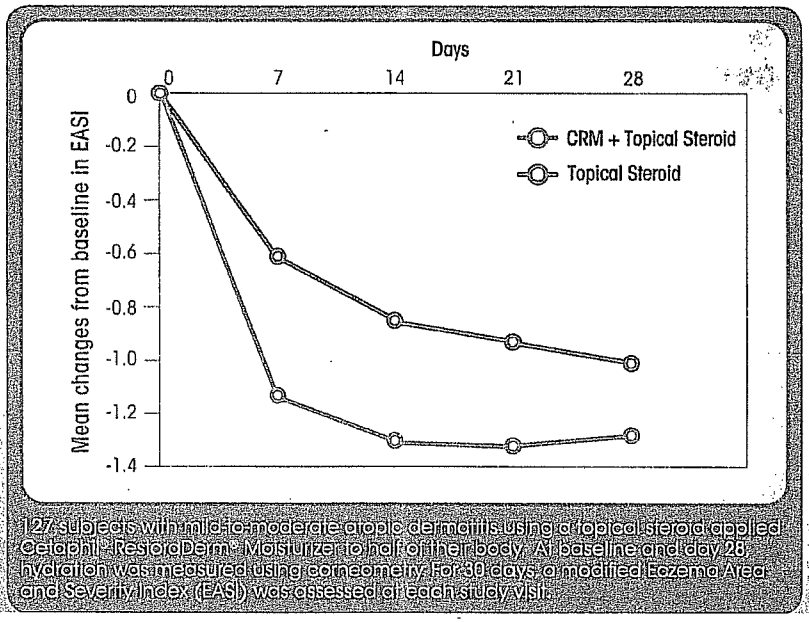


127 subjects with mild-to-moderate atopic dermatitis using a topical steroid applied Cetaphil® RestoraDerm® Moisturizer to half of their body. At baseline and day 28, hydration was measured using corneometry (n=42).

Cetaphil® RestoraDerm® Moisturizer

Increases hydration when used with a topical steroid[3]

Decrease in overall disease severity compared with topical steroid treatment alone[3,5]



127 subjects with mild-to-moderate atopic dermatitis using a topical steroid applied Cetaphil® RestoraDerm® Moisturizer to half of their body. At baseline and day 28, hydration was measured using corneometry. For 28 days, a modified Eczema Area and Severity Index (EASI) was assessed at each study visit.

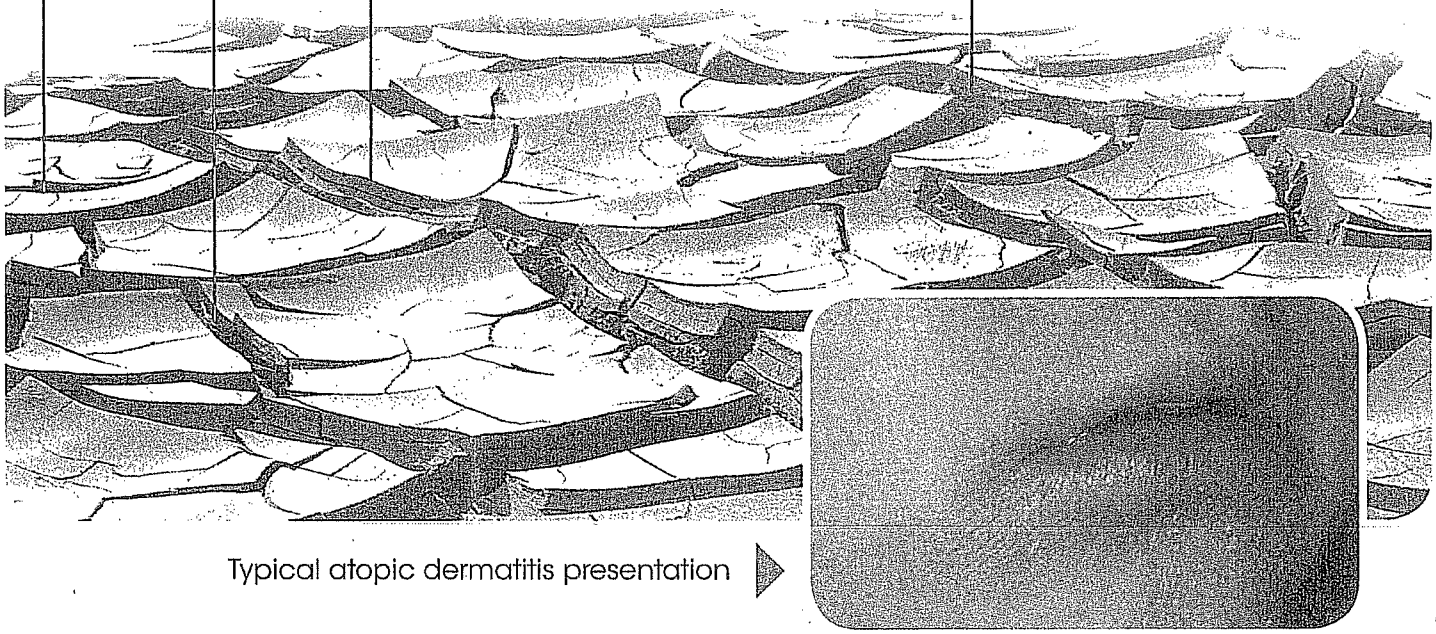
The Eczema Area and Severity Index (EASI)

A tool to measure the severity of atopic dermatitis

Structural deficiencies can lead to a compromised skin barrier in atopic dermatitis

Atopic skin may be deficient in filaggrin proteins and ceramides[1,2]

- Lack of filaggrin proteins can result in fewer breakdown products[1]
  - Filaggrin breakdown products are needed to form natural moisturizing factor (NMF)[1]
    - A reduction of filaggrin-generated NMF results in reduced hydration and suppleness in the skin barrier[1]
- Reduced levels of ceramides 1 and 3 cause excess water loss from the damaged skin barrier[2]



Typical atopic dermatitis presentation

Photo provided by Dr. Joseph Bikowski

Help rebuild the skin barrier with a skincare regimen including Cetaphil® RestoraDerm® products

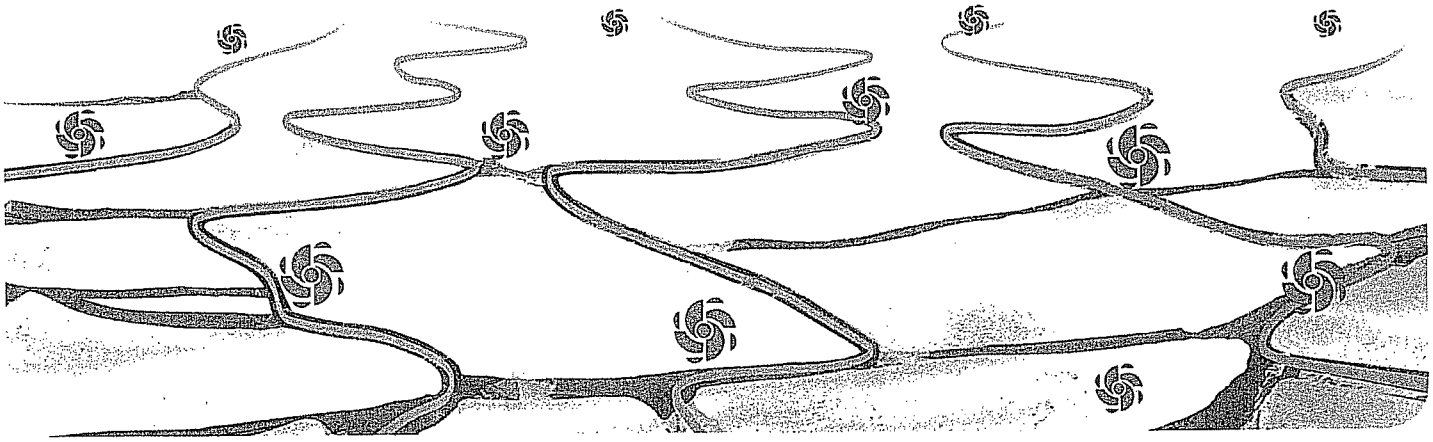
The first and only products with both ceramide and Filaggrin technology™

Filaggrin technology™

- Contains filaggrin breakdown products (sodium PCA and arginine) that help replenish NMF[2,3]
- Leads to improved hydration, which helps restore skin barrier function[4]

Ceramide technology

- Increases ceramides 1, 2 and 3[5]
- Helps the skin retain moisture[5]



Proven to significantly restore skin barrier function (compared with baseline) over 4 weeks

- Decreased transepidermal water loss (TEWL) and increased hydration as assessed by corneometry[4]

Uniquely formulated to meet the needs of your atopic dermatitis patients

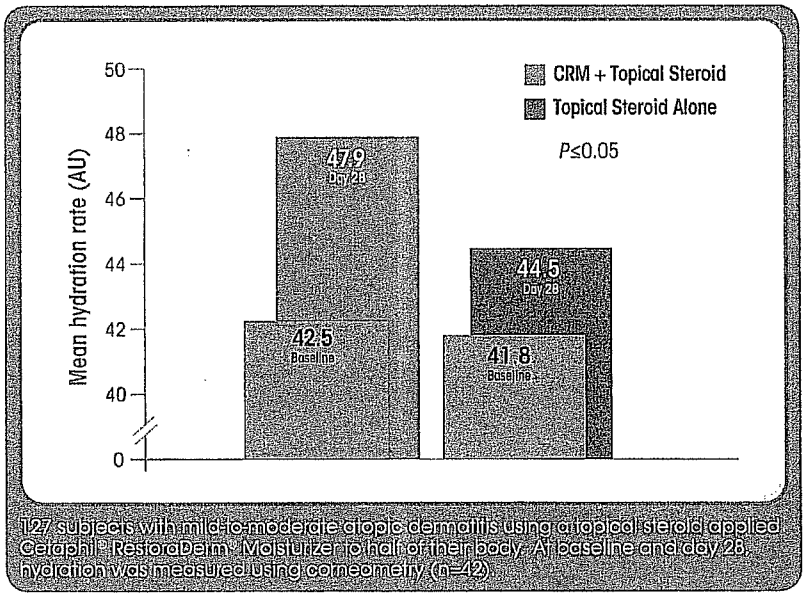
- Soothes the dry, itchy skin of eczema[4]
- Proven highly tolerable on atopic skin[4]

Cetaphil® RESTORADERM®

Improves hydration and decreases overall disease severity

Newly published data[3] for Cetaphil® RestoraDerm® Moisturizer

Significant hydration versus topical steroid treatment alone[3,4]



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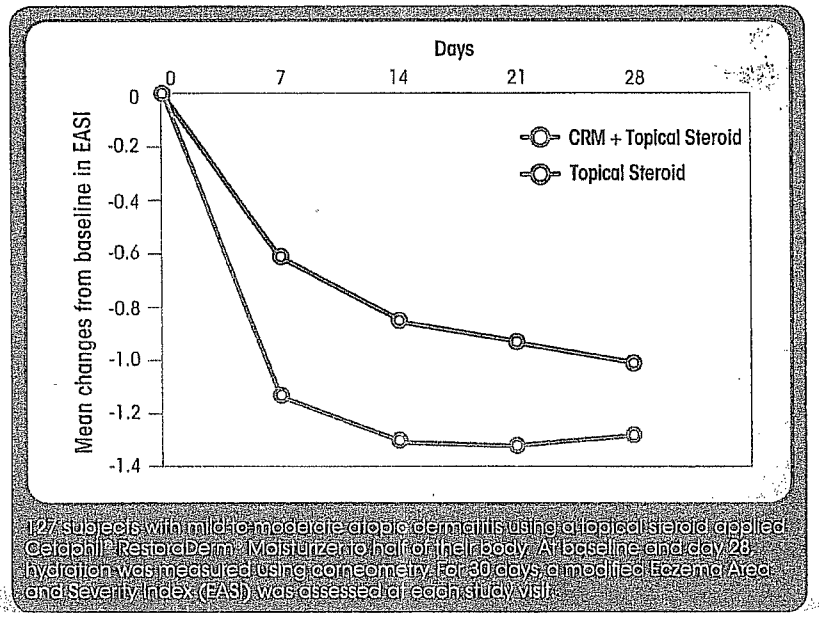
Cetaphil® RestoraDerm® Moisturizer

Increases hydration when used with a topical steroid[3]

Decrease in overall disease severity compared with topical steroid treatment alone[3,4]



127 subjects with mild-to-moderate atopic dermatitis using a topical steroid applied Cetaphil® RestoraDerm® Moisturizer to half of their body. At baseline and day 28, hydration was measured using corneometry. For 30 days, a modified Eczema Area and Severity Index (EASI) was assessed at each study visit.

The Eczema Area and Severity Index (EASI)

A tool to measure the severity of atopic dermatitis

Recommend Cetaphil® RestoraDerm® Body Wash and Moisturizer:

the first and only products with both ceramide and Filaggrin technology™

- Unique formulation contains ceramides and filaggrin breakdown products needed to restore and moisturize the compromised skin barrier[2-5]
- Proven results in atopic patients—soothes the dry, itchy skin of eczema[4]

Typical atopic dermatitis presentation

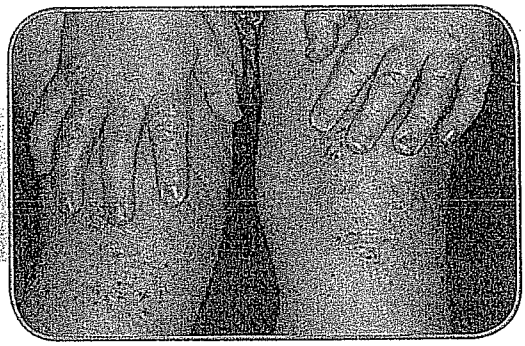


Photo provided by Dr. Joseph Bikowski

Cetaphil® RestoraDerm® products: SEE. SAMPLE. SEND.

SEE patients with atopic dermatitis

SAMPLE with a recommendation and a coupon for Cetaphil® RestoraDerm® products

SEND patients to CVS®, Walgreens®, Target® or Walmart® to purchase

Cetaphil® RESTORADERM®

Replenish. Restore. Rebuild.

References: 1. Chandar P, Nole G, Johnson AW. Understanding natural moisturizing mechanisms: implications for moisturizer technology. *Cutis*. 2009;84(suppl 1):2-15. 2. Sugarman JL. The epidermal barrier in atopic dermatitis. *Semin Cutan Med Surg*. 2008;27:108-114. 3. Simpson E, Dutronc Y. A new body moisturizer increases skin hydration and improves atopic dermatitis symptoms among children and adults. *J Drugs Dermatol*. 2011;10:744-749. 4. Data on file, Galderma Laboratories. 5. Castiel-Higounenc I, Chopart M, Ferraris C. Stratum corneum lipids: specificity, role, deficiencies and modulation. *OCL*. 2004;11(6):401-406.

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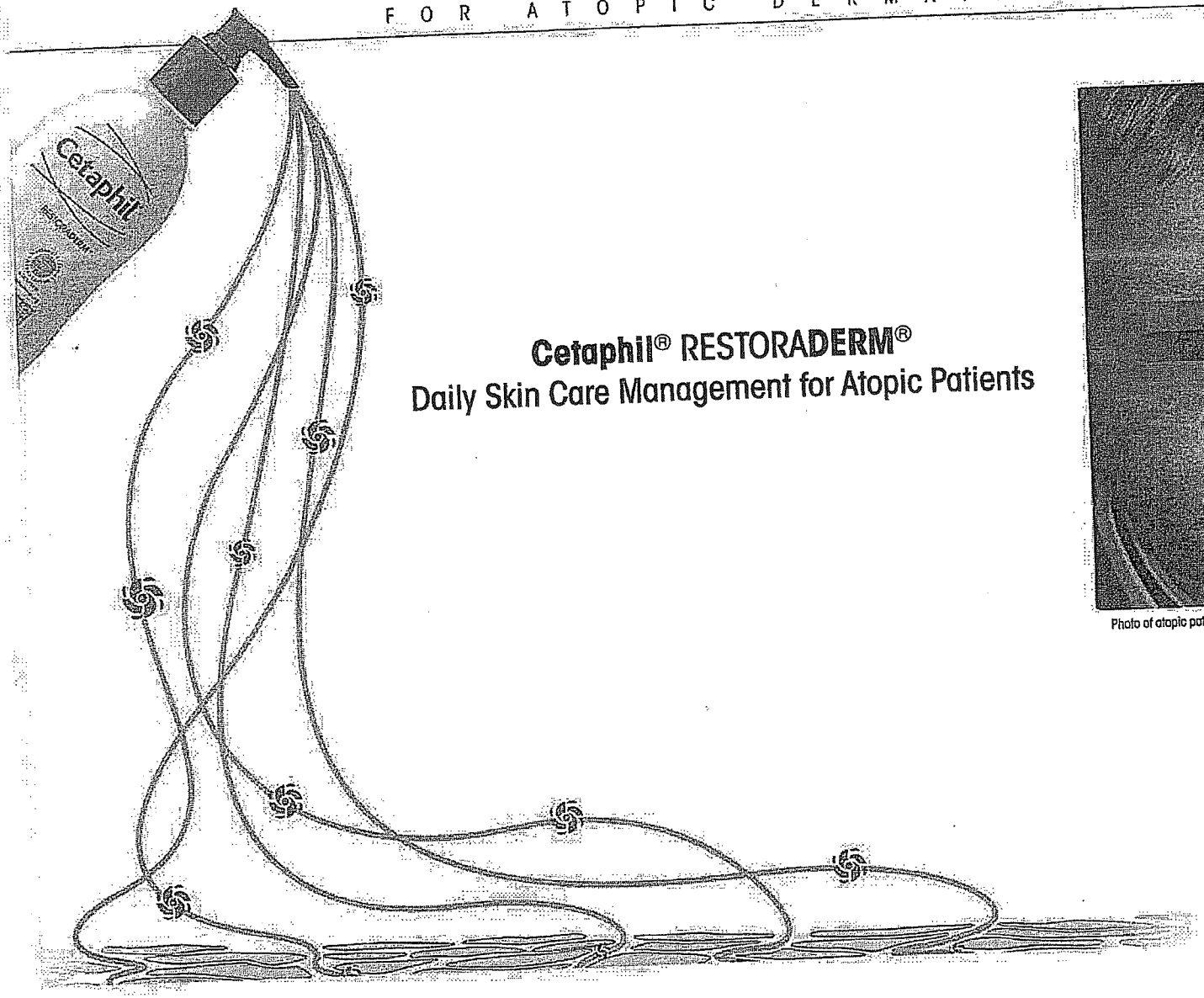
FOR ATOPIC DERMATITIS



Cetaphil® RESTORADERM®
Daily Skin Care Management for Atopic Patients

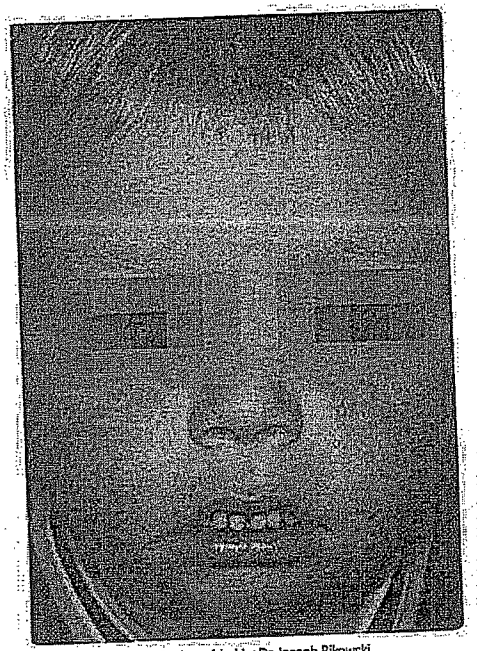


Photo of atopic patient provided by Dr Joseph Bikowski.

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PUBLIC

~ Atopic dermatitis is the most common childhood skin disease, affecting approximately 20% of children in the US

~ Approximately 65% of patients develop symptoms in the first year of life

Common skin signs and symptoms

~ Dryness ~ Itch ~ Swelling ~ Redness
~ Cracking ~ Crusting ~ Scaling

Atopic dermatitis can take a toll on both patient and family

~ Lack of sleep ~ Behavioral problems ~ Multiple doctor visits
~ Low self-esteem ~ Medication expenses

Question: *What is the most common symptom of atopic dermatitis?*

Answer: *Dry, itchy skin*

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PUBLIC

Atopic dermatitis: A chronic skin disease with significant impact

- The most common childhood skin disease, affects approximately 20% of children in the US[1]
- Approximately 65% of patients develop symptoms in the first year of life[2]

Common skin signs and symptoms[2]

- Dryness
- Itch
- Swelling
- Redness
- Cracking
- Crusting
- Scaling

Atopic dermatitis can take a toll on both patient and family[2,3]

- Lack of sleep
- Low self-esteem
- Behavioral problems
- Medication expenses
- Multiple doctor visits

Atopic dermatitis is typically found on face, inside of elbows, behind knees, and on hands and feet.

Photo of atopic patient provided by Dr Joseph Bikowski

In a skin care survey, approximately 52% of mothers described their children with eczema as being irritable.[1]

From the survey *Skin Care Preferences and Dealing With Eczema*, conducted with over 1000 mothers of children with eczema in the US in June 2010.

Atopic Dermatitis

Cetaphil RESTORADERM

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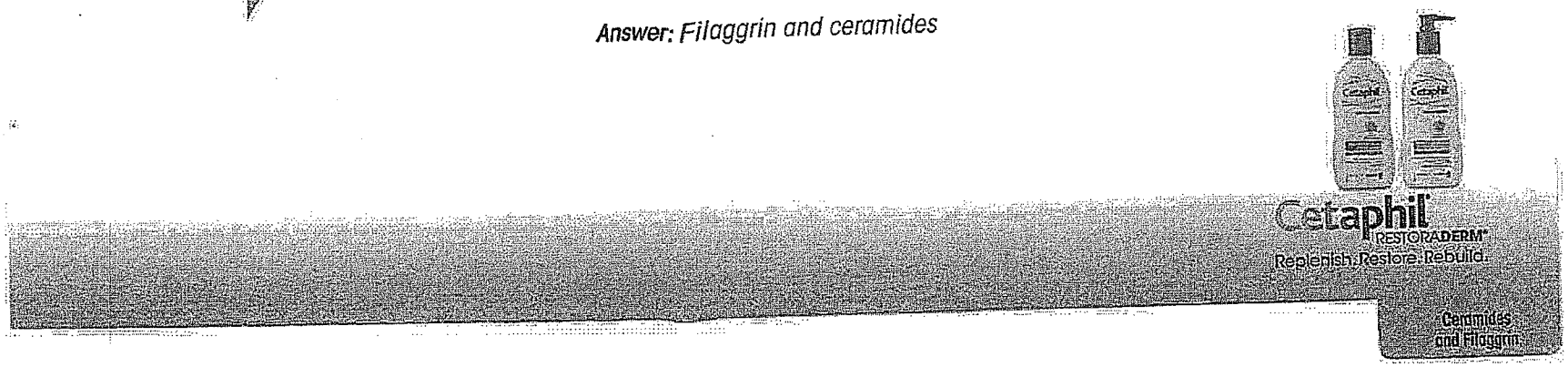
- ~ A lipid is a fat or oil that has moisture-binding properties
- ~ A protein is composed of amino acids and is associated with growth, repair and maintenance of cells
- ~ The stratum corneum contains lipids and proteins called ceramides and filaggrin
- ~ Atopic skin is deficient in filaggrin and ceramides, resulting in a damaged skin barrier
- ~ Reduced level of ceramides results in a damaged skin barrier and excessive water loss
- ~ Filaggrin deficiency compromises barrier function, leaving skin vulnerable to irritants and allergens

Question: *Deficiencies in what two elements are associated with atopic dermatitis?*

Answer: *Filaggrin and ceramides*



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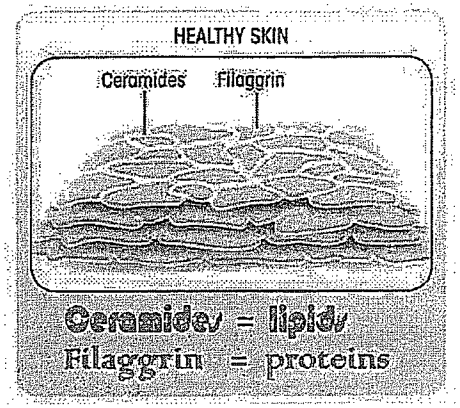
Two key elements of healthy skin

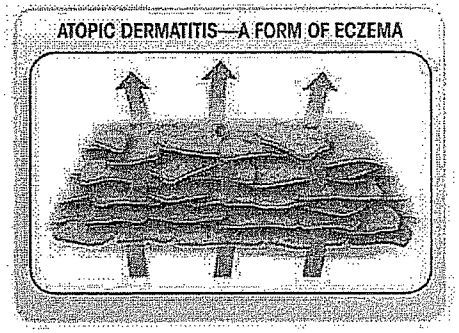
- A lipid is a fat or oil that has moisture-binding properties[4,5]
- A protein is composed of amino acids and is associated with growth, repair and maintenance of cells[4]
- The stratum corneum contains lipids and proteins called ceramides and filaggrin[6]

Atopic skin is deficient in filaggrin and ceramides

- Reduced level of ceramides results in a damaged skin barrier and excessive water loss[6]
- Filaggrin deficiency compromises barrier function, leaving skin vulnerable to irritants and allergens[6]

Photo of atopic patient provided by Dr Joseph Bikowski.





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Ceramides and Filaggrin

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Medication is often prescribed to atopic patients. Daily skin care also plays an important role in the management of atopic dermatitis. Deficiencies in moisture and barrier protection are key factors in atopic skin.

- The first and only products with ceramide and Filaggrin technology™, **Cetaphil®** RESTORA**DERM®** products' patented technology helps restore hydration in atopic skin
- Filaggrin technology™ restores moisture to help rebuild the damaged skin barrier
- Ceramides help replenish the skin's natural lipids
- **Cetaphil®** RESTORA**DERM® Skin Restoring Moisturizer** is clinically proven to help restore skin barrier function
  - Improves surface hydration as early as day 1
  - Provides long-lasting hydration for atopic skin
- **Cetaphil®** RESTORA**DERM® Skin Restoring Body Wash** encapsulates skin-nourishing oils in a soap-free foaming wash
  - Helps soothe itch and reduce redness, dryness and irritation
  - Significantly decreases burning, stinging, scaling and flaking

Question: ***What unique technology in Cetaphil® RESTORADERM® products restores moisture to help rebuild the damaged skin barrier?***

Answer: Filaggrin technology™

Cetaphil RESTORADERM®
Replenish. Restore. Rebuild.
Ceramide & Filaggrin Technology™ Efficacy

PUBLIC

Medication is often prescribed to atopic patients. Daily skin care also plays an important role in the management of atopic dermatitis. Deficiencies in moisture and barrier protection are key factors in atopic skin.

The first and only products with ceramide and Filaggrin technology™, Cetaphil® RESTORADERM® products' patented technology helps restore hydration in atopic skin

- Filaggrin technology™ restores moisture to help rebuild the damaged skin barrier[1]
- Ceramides help replenish the skin's natural lipids[6]

- Helps restore skin barrier function[1]
- Improves surface hydration[1]
- Provides long-lasting hydration[1]

- Soap-free foaming wash
- Helps soothe itch and reduce redness, dryness and irritation[1]
- Significantly decreases burning, stinging and scaling[1]

Cetaphil® RESTORADERM®

Replenish. Restore. Rebuild.

Ceramide & Filaggrin Technology™/Efficacy

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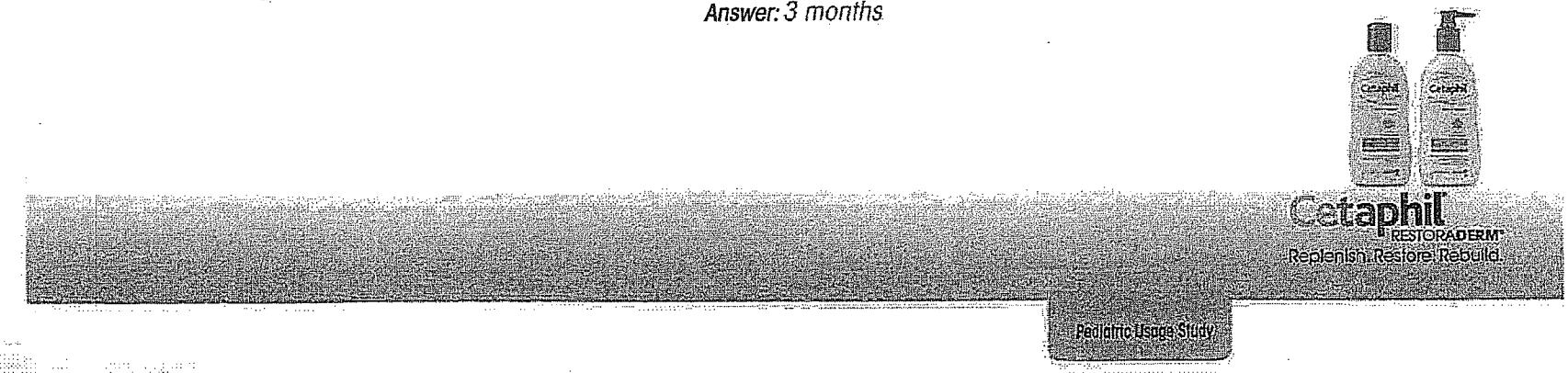
- The safety and tolerability of **Cetaphil® RESTORADERM®** products were evaluated in 53 patients, aged 3–36 months, with atopic tendencies
- Patients were bathed and moisturized at least once a day, but no more than twice daily for 4 weeks
- Additionally, skin barrier function, or transepidermal water loss (TEWL), and hydration (corneometry) were measured in triplicate at baseline and at weeks 2 and 4, at least 2.5 hours after application of product
- Approximately 90% of subjects had no scaling or dryness after using **Cetaphil® RESTORADERM® Moisturizer and Body Wash**
- 92% reported that the regimen was non-irritating
- 87% of survey respondents in the study agree that the regimen relieves itchy skin

Question: **Cetaphil® RESTORADERM®** *products have been proven safe for use in children as young as ____?*

Answer: 3 months



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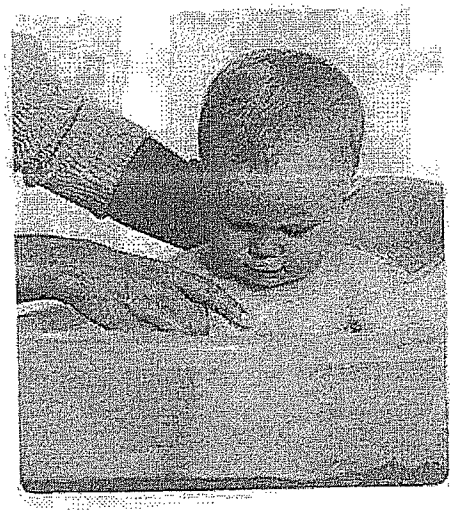
Pediatric Usage Study

Safety and tolerability demonstrated in Cetaphil® RESTORADERM® Skin Restoring Moisturizer and Body Wash



Study design

- Safety and tolerability evaluated in 53 patients, aged 3-36 months, with atopic tendencies[1]
- Patients bathed and moisturized at least once a day, but no more than twice daily, for 4 weeks[1]
- Additionally, skin barrier function (TEWL) and hydration (corneometry) measured three times: at baseline, week 2 and week 4[1]

Proven tolerability, with a high degree of patient satisfaction

- Approximately 90% of subjects had no scaling or dryness after use[1]
- 92% reported that the regimen was non-irritating[1]
- 87% of survey respondents in the study agree that the regimen relieves itchy skin[1]

Cetaphil® RESTORADERM®

Replenish. Restore. Rebuild.

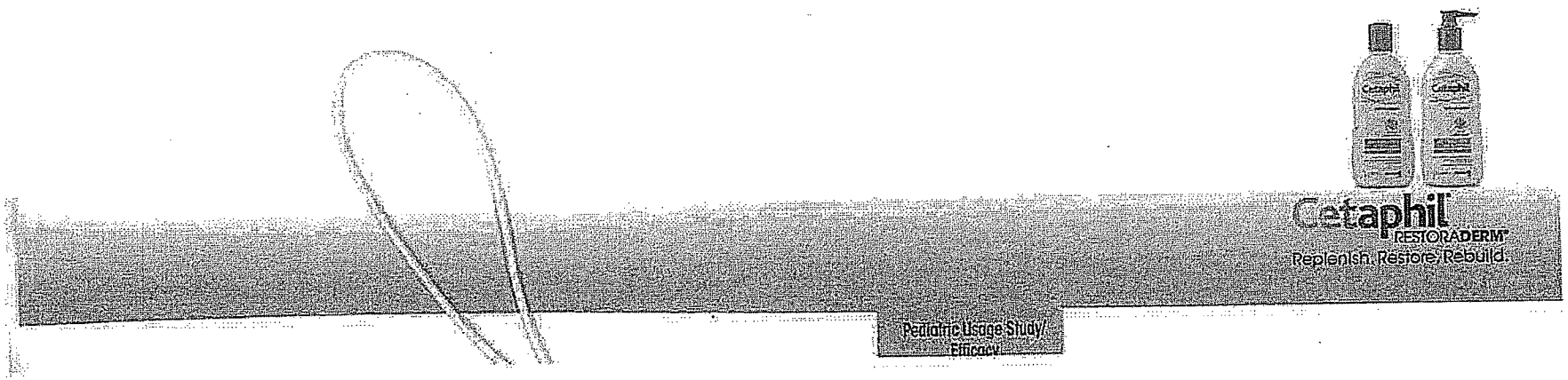
PUBLIC

~ **Cetaphil® RESTORADERM® Skin Restoring Moisturizer and Body Wash** improve skin barrier function

~ **Cetaphil® RESTORADERM®** products significantly decreased TEWL scores when compared with baseline measurements at 2 weeks and 4 weeks of treatment

~ **Cetaphil® RESTORADERM® Skin Restoring Moisturizer and Body Wash** improve hydration

~ **Cetaphil® RESTORADERM®** products significantly increased hydration compared with baseline measurements, as assessed by corneometry



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Cetaphil® RESTORADERM® Skin Restoring Moisturizer and Body Wash

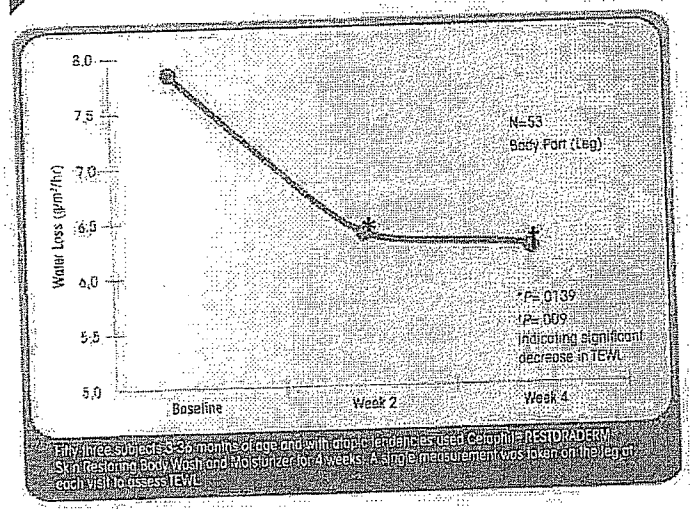
Improves skin barrier function

Cetaphil® RESTORADERM® Moisturizer and Body Wash significantly decreased TEWL at 2 weeks and 4 weeks compared with baseline[1]

Improves hydration

Cetaphil® RESTORADERM® products significantly increased hydration compared with baseline measurements, as assessed by corneometry[1]

Improves skin barrier function over 4 weeks[1]



Fifty-three subjects (≥ 3 months of age and with dry skin) applied Cetaphil RESTORADERM Skin Restoring Body Wash and Moisturizer for 4 weeks. A single measurement was performed per visit to assess TEWL

Cetaphil® RESTORADERM®
Replenish. Restore. Rebuild.

Pediatric Usage Study

PUBLIC

Cetaphil® RESTORADERM® products

- ~ Proven non-irritating on atopic skin
- ~ Safe for use in children as young as 3 months of age
- ~ Contain no preservatives, fragrances, nut oils, parabens or lanolin
- ~ Steroid free

Question: *True or false:* **Cetaphil® RESTORADERM®** *products contain no preservatives, fragrances, nut oils, parabens or lanolin.*

Answer: True

Cetaphil RESTORADERM®
Replenish. Restore. Rebuild.

Tolerability/
Safety Profile

PUBLIC

Cetaphil® RESTORADERM® products are proven non-irritating on atopic skin

~ Safe for use in children as young as 3 months

~ Contain no preservatives, fragrances, nut oils, parabens or lanolin

~ Steroid free

Contact with eyes should be avoided

Complete formula for atopic skin

	Formulated for Atopic Skin	Ceramides	Filaggrin Proteins	Niacinamide	Sunflower Seed Oil	Glycerin	Shea Butter
Cetaphil® RESTORADERM® Skin Restoring Moisturizer	✓	✓	✓	✓	✓	✓	✓
Cetaphil® RESTORADERM® Skin Restoring Body Wash	✓		✓	✓	✓	✓	✓
CeraVe® Body Moisturizers and Cleanser		✓				✓	
Eucerin® Calming Crème						✓	
Aveeno® Advanced Care		✓				✓	

"I absolutely love the products. Helped with my itchy dry skin. Will definitely purchase both items."†

†User testimonials were gathered as part of a patient-experience program, in which participants were given Cetaphil® RESTORADERM® products by their doctor and asked to share their experiences after 1 week of use (n=408).

Cetaphil® RESTORADERM®
Replenish. Restore. Rebuild.

Tolerability/ Safety Profile

PUBLIC

- ~ The first and only products to contain patented ceramide and Filaggrin technology™
  - — Ceramides help replenish the skin's natural lipids
  - — Filaggrin technology™ helps restore moisture to help rebuild the damaged skin barrier
- ~ Clinically proven to help soothe itch and reduce redness, dryness and irritation
- ~ Safe for use in children as young as 3 months of age
- ~ Contain no preservatives, fragrances, nut oils, parabens or lanolin

Make Cetaphil® RESTORADERM® the foundation of a daily skin care regimen for your patients with atopic dermatitis

QUIZ

Question: 1 *What is the most common symptom of atopic dermatitis?*

Answer: Dry, itchy skin

Question: 2 *Deficiencies of what two elements are associated with atopic dermatitis?*

Answer: Filaggrin and ceramides

Question: 3 *What unique technology in* **Cetaphil® RESTORADERM®** *products restores moisture to help rebuild the damaged skin barrier?*

Answer: Filaggrin technology™

Question: 4 **Cetaphil® RESTORADERM®** *products have been proven safe for use in children as young as ____?*

Answer: 3 months

Question: 5 *True or false:* **Cetaphil® RESTORADERM®** *products contain no preservatives, fragrances, nut oils, parabens or lanolin.*

Answer: True

Cetaphil® RESTORADERM™
Replenish. Restore. Rebuild.

Summary

PUBLIC

Cetaphil® RESTORADERM® Skin Restoring Moisturizer and Body Wash: Patented technology helps restore hydration in atopic skin

- The first and only products to contain patented ceramide and Filaggrin technology™
- Clinically proven to help soothe itch and reduce redness, dryness and irritation
- Safe for use in children as young as 3 months of age
- Contain no preservatives, fragrances, nut oils, parabens or lanolin

Replenish. Restore. Rebuild.

Make Cetaphil® RESTORADERM® the foundation of a daily skin care regimen for your patients with atopic dermatitis

Available at locations nationwide

"Better results than any cream or body wash used previously."†

†User testimonials were gathered as part of a patient-experience program, in which participants were given **Cetaphil®** RESTORA**DERM®** products by their doctor and asked to share their experiences after 1 week of use (n=408).

Cetaphil® RESTORADERM®
Replenish. Restore. Rebuild.

Summary

PUBLIC

Cetaphil® RESTORADERM® Skin Restoring Moisturizer

~ Clinically proven to help restore skin barrier function

~ Improves surface hydration as early as day 1

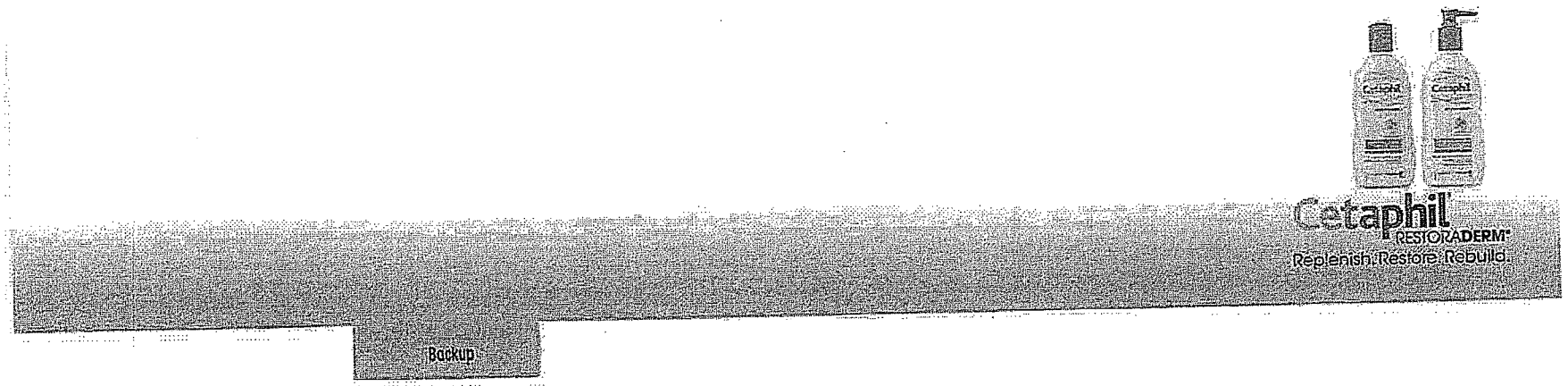
~ Provides long-lasting hydration for atopic skin

Cetaphil® RESTORADERM® Skin Restoring Body Wash

~ Encapsulates skin-nourishing oils in a soap-free foaming wash

~ Helps soothe itch and reduce redness, dryness and irritation

~ Significantly decreases burning, stinging and scaling



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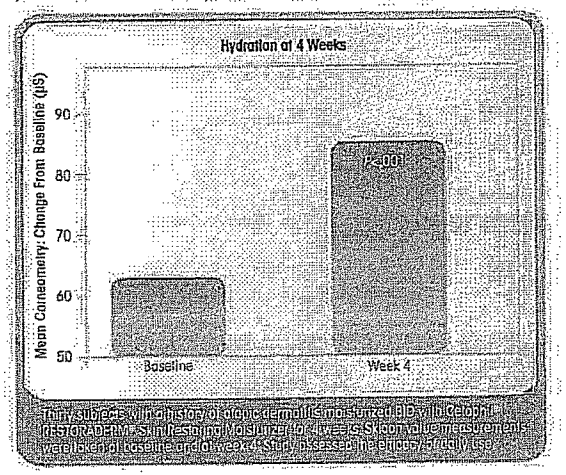
Cetaphil® RESTORADERM® Skin Restoring Moisturizer

- ~ Helps restore skin barrier function
- ~ Improves surface hydration
- ~ Long-lasting hydration

Significantly increased hydration after 4 weeks[1]

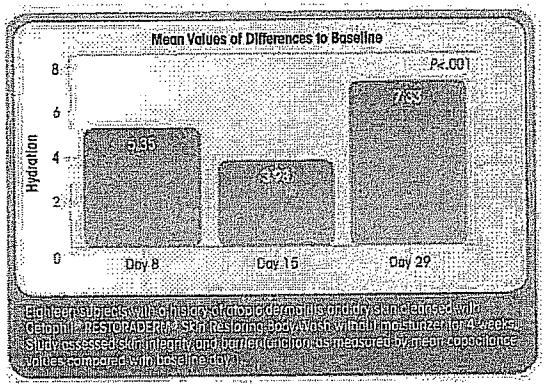


Thirty subjects with history of atopic dermatitis moisturized daily with Cetaphil RESTORADERM Skin Restoring Moisturizer for 4 weeks. Serial volume measurements were taken at baseline and at 4 weeks. Study assessed in the primary facility used.

Cetaphil® RESTORADERM® Skin Restoring Body Wash

- ~ Soap-free foaming wash
- ~ Helps soothe itch and reduce redness, dryness and irritation
- ~ Significantly decreases burning, stinging and scaling

Cleanses without disrupting skin's ability to retain moisture[1]



Eighteen subjects with history of atopic dermatitis randomly cleansed with Cetaphil RESTORADERM Skin Restoring Body Wash with moisturizer for 4 weeks. Study assessed skin integrity and hydration as measured by transepidermal water loss compared with baseline readings.

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Backup

PUBLIC

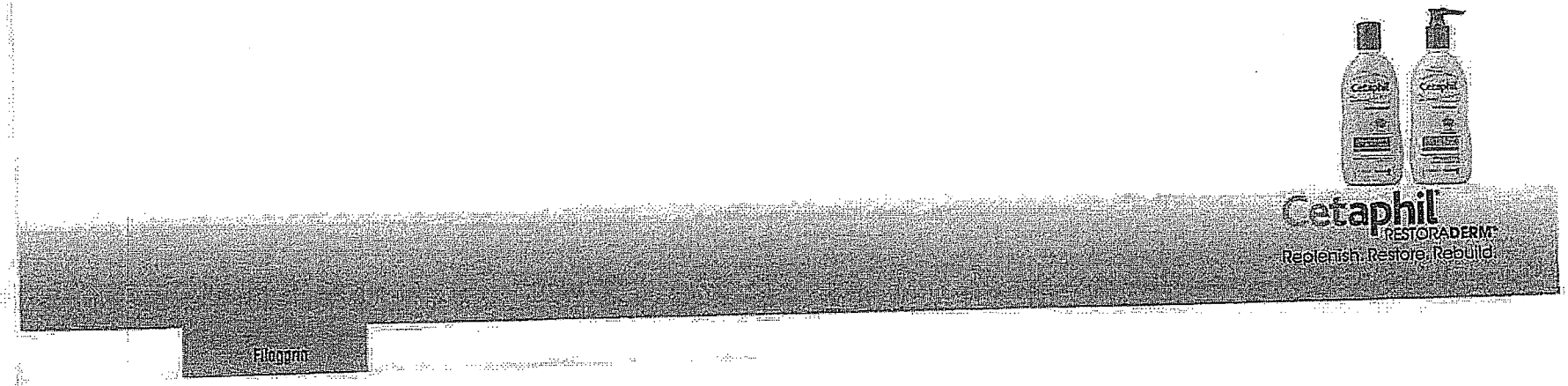
~ Filaggrin is broken down into filaggrin breakdown products (free amino acids)

~ These amino acids bond with other chemicals to form natural moisturizing factors (NMFs)

~ Filaggrin-generated NMFs hold water to keep the stratum corneum hydrated and supple

Ceramides: The brick and mortar model

~ Ceramides are essential to help hold moisture within skin and help cells stay together



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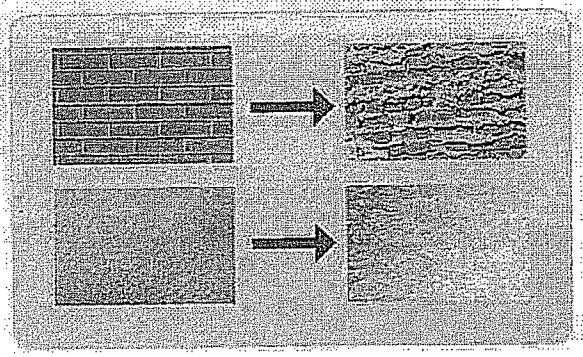
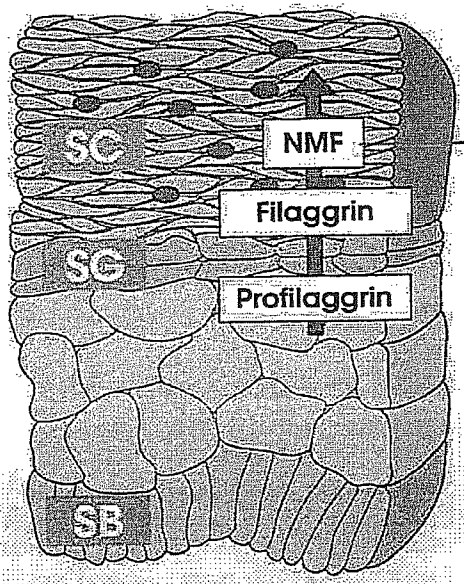
Filaggrin—a closer look

- Filaggrin is broken down into filaggrin breakdown products (free amino acids)[7]
- These amino acids bond with other chemicals to form natural moisturizing factors (NMFs)[7]
- Filaggrin-generated NMFs hold water to keep the stratum corneum hydrated and supple[7]

Ceramides: The brick and mortar model

- Ceramides are essential to help hold moisture within skin and help cells stay together[7]





NMFs are also known as filaggrin breakdown products

– 40% of NMFs are arginine and sodium PCA[7]

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Filaggrin

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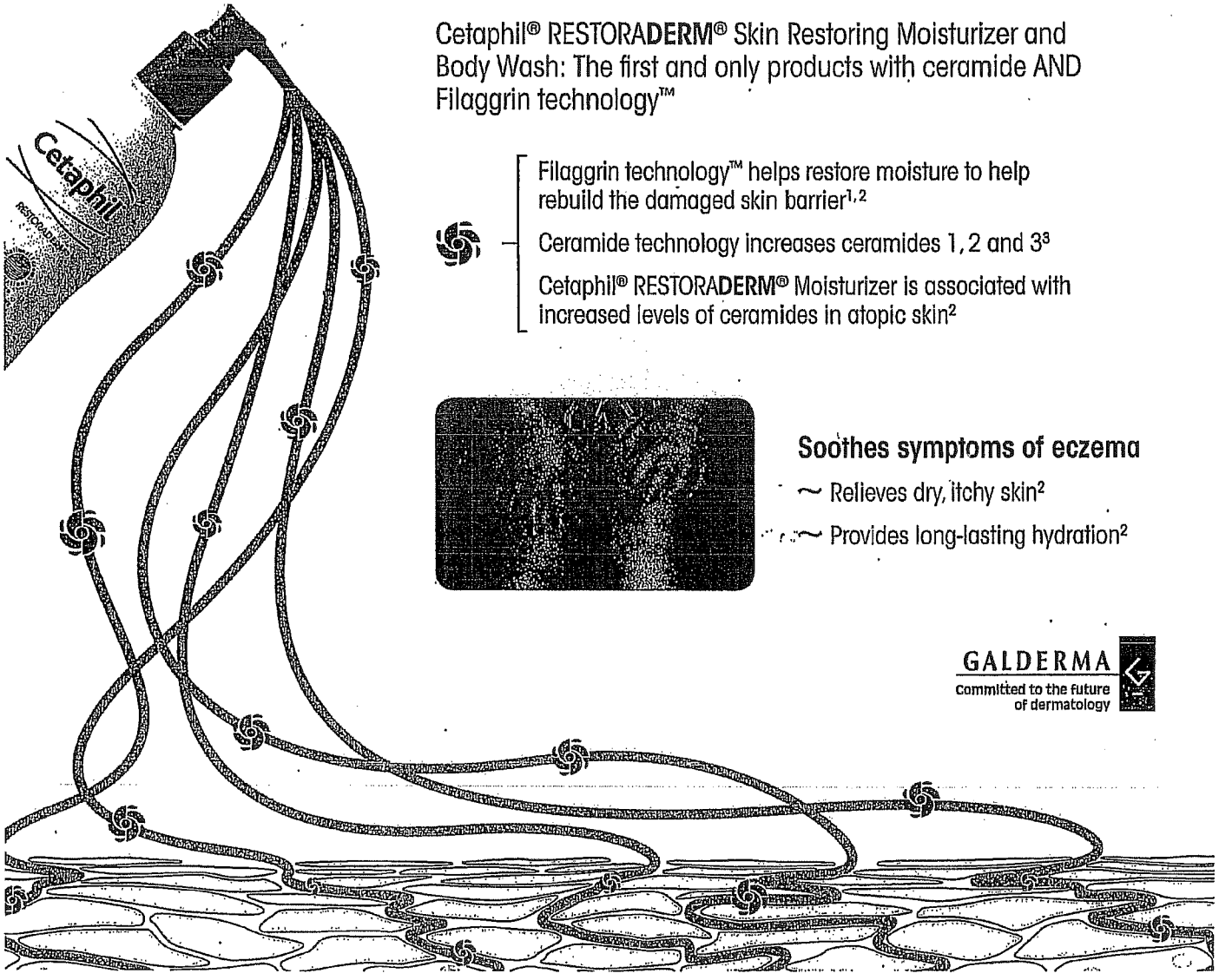
ATOPIC DERMATITIS: Results in skin barrier dysfunction

Filaggrin: A protein deficiency in atopic skin

~ Filaggrin deficiency compromises barrier function, leaving skin vulnerable to irritants and allergens[1]

Ceramides: Lipid deficiency in atopic skin

~ Reduced levels of ceramides 1 and 3 cause excess water loss and a damaged skin barrier[1]



Cetaphil® RESTORADERM® Skin Restoring Moisturizer and Body Wash: The first and only products with ceramide AND Filaggrin technology™

- Filaggrin technology™ helps restore moisture to help rebuild the damaged skin barrier[1,2]
- Ceramide technology increases ceramides 1, 2 and 3[3]
- Cetaphil® RESTORADERM® Moisturizer is associated with increased levels of ceramides in atopic skin[2]

Soothes symptoms of eczema

~ Relieves dry, itchy skin[2]

~ Provides long-lasting hydration[2]

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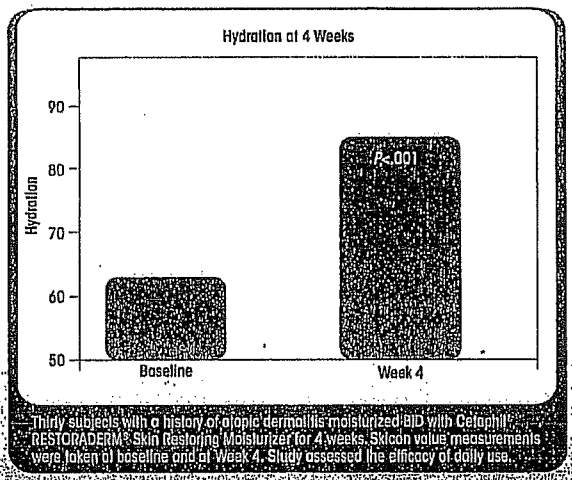
Proven results in atopic patients

Cetaphil® RESTORADERM® Skin Restoring Moisturizer

▶ Significantly increased hydration after 4 weeks[2]



Thirty subjects with a history of atopic dermatitis moisturized BID with Cetaphil® RESTORADERM® Skin Restoring Moisturizer for 4 weeks. Skicon value measurements were taken at baseline and at Week 4. Study assessed the efficacy of daily use.

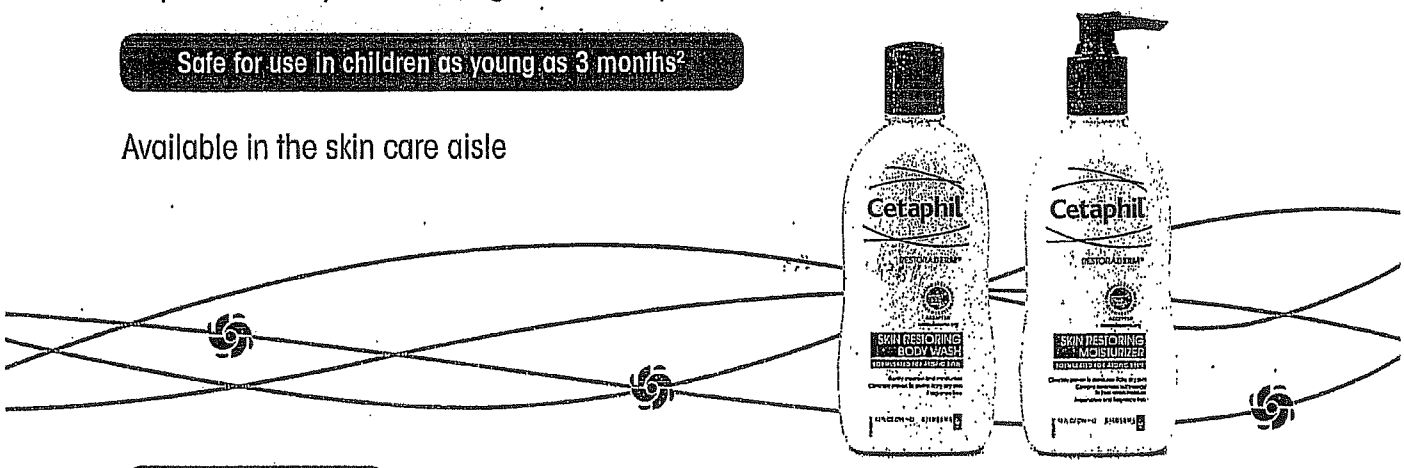
Cetaphil® RESTORADERM® Skin Restoring Moisturizer

- ~ Clinically proven to help restore skin barrier function[2]
- ~ Improves surface hydration as early as Day 1[2]
- ~ Provides long-lasting hydration for atopic skin[2]

Recommend Cetaphil® RESTORADERM® products as part of a daily skin care regimen for atopic skin

Safe for use in children as young as 3 months[2]

Available in the skin care aisle



#1 DERMATOLOGIST RECOMMENDED BRAND OF CLEANSERS AND MOISTURIZERS

Cetaphil® RESTORADERM®

Replenish. Restore. Rebuild.

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References: 1. Sugarman JL. The epidermal barrier in atopic dermatitis. *Semin Cutan Med Surg.* 2006;27:108-114. 2. Data on file. Galderma Laboratories. 3. Castiel-Higounenc I, Chopart M, Ferrari C. Stratum corneum lipids: specificity, role, deficiencies and modulation. *OCL.* 2004;11(6):401-406.
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