

ROSACEA

Prevalence

Rosacea may affect up to 14 million adult Americans. Even though it is so common, only 1 in 4 people have heard of it. It affects more women than men, but more men seek treatment for severe disease. More men develop the advanced sequelae of severe telangiectasias (dilated blood vessels) and rhinophyma (red, bulbous nose). Rosacea begins between the ages of 30 and 50, although the first stages may be barely detectable by the patient and not at all by others. The most common age for onset is in the 40s and 50s.

The vascular reactivity seen in rosacea is most common in fair-skinned individuals of Irish and Scandinavian descent. It is seen in persons who blush easily, i.e. already have vascular hyper-reactivity.

Etiology (Cause) and Progression of Disease

The cause of rosacea lies with hyper-responsiveness of the blood vessels of the central face. Why some people develop rosacea and others do not is really unknown. Alcohol was once thought to be causative, but has never been proven to be directly linked to the development of the disease. However, alcohol does cause vasodilatation and serves as a disease trigger. Rosacea is a chronic and progressive disease with many flare-ups and remissions.

Sebaceous plugging is not causative in rosacea as it is in acne. There may be bacterial overgrowth as the disease becomes more severe, but the presence of bacteria is also not causative as in acne.

The first stage of rosacea is merely a vascular hyper-reactivity or tendency for the central face to redden easily. This can occur in the 20s or 30s and is usually not identified as rosacea. In fact, rosacea progresses so gradually that it may go completely undiagnosed, even after the facial changes are obvious. The early stage is almost impossible to treat, except by avoiding some triggers (listed below) in particular individuals. During the course of rosacea, at least 50% of patients have some type of ocular (eye) symptom. The eye symptoms can also be found in this first stage and may be the only symptom the patient notices. Eye symptoms are frequently found as the disease progresses. Eye complaints may include dry eye, stye development, contact lens intolerance, redness of the eyelids or even corneal damage. When the patient only complains of eye symptoms, the term 'ocular rosacea' is sometimes used.

After this initial stage of intermittent facial flushing, the disease progresses to constant erythema (redness) of the central face and ocular (eye) symptoms, then papule and pustule development, appearance of telangiectasias (dilated blood vessels) and, finally, rhinophyma (a red, bulbous nose which was typified by W. C. Fields). Rhinophyma is certainly disfiguring and even the pustular/papular stage is very unattractive. The skin and subcutaneous (just below the skin) tissue of the nose is affected by rhinophyma but the supporting structures of cartilage and bone remain intact and are not affected. The lack of involvement of the supporting framework of the nose makes rhinophyma more amenable to surgical treatment than it would be if these structures were affected.

Common symptoms of rosacea include facial flushing progressing to persistent facial redness of the cheeks, forehead, chin and nose, red lines on the face (telangiectasias), stinging or burning of the face, increased pore size, red bumps or pimples on the central facial skin, nasal bumps that increase in

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number and size until rhinophyma develops. Rosacea can be considered an age-related disease. Even though the very first symptoms of disease can appear in the 20s, 30s or 40s, most people are not actually diagnosed as having rosacea until their 40s and 50s.

Misdiagnosis of Rosacea

Rosacea is commonly misdiagnosed. Rosacea is NOT acne, although this is the most common mislabeling that occurs. The cause of rosacea is different from that of acne. Some of the drugs used for rosacea are also used to treat acne and this may add to its confusion with acne.

Tumors, such as lymphoma, basal cell carcinoma of the nose or face, and squamous cell carcinoma of the nose or face may be confused with rosacea in its later stages. This can have disastrous consequences for the patient, leaving a potentially treatable condition to progress to a more serious stage that is much more difficult to treat or may even be untreatable.

Sarcoid presenting in the nose can appear to be rosacea.

Because alcohol as a triggering factor has been known for some time, persons with rosacea used to be assumed to be alcoholics. The occurrence of rosacea does NOT mean the person is an alcoholic.

Disease Triggers

The following substances are known to trigger the disease, although this occurs with varying frequency. The most well-known trigger is alcohol. It should be emphasized again that the occurrence of rosacea should not label the person an alcoholic. The presence of rosacea, however, will cause the physician to recommend avoidance of alcohol since this is such a common trigger.

Foods are also common triggers. Individual food triggers include hot peppers, Mexican food, Thai food, red pepper, hot sausage, black pepper, vinegar, paprika, white pepper and garlic. These foods are listed from most frequent and in descending order of frequency for triggering rosacea. Very hot beverages may be a trigger in some patients. Note that these foods are also known for causing vasodilatation, which would lead to flushing.

Other potential triggers are environmental, such as sun exposure and cold weather. Stress may also trigger an exacerbation of symptoms.

Treatment

The first line of treatment is to avoid any triggering or exacerbating factors. Topical antibiotics may be used long-term. Topical retinoid (Renova) therapy may be used as well as systemic treatment with oral antibiotics. Surgery (as laser therapy or other techniques) may be used for unsightly telangiectasias or rhinophyma.

Product Recommendations

iS CLINICAL[®] products recommended for rosacea include: PRO-HEAL[™] SERUM ADVANCE+ and HYDRA-COOL[™] SERUM.

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Introducing iS CLINICAL® ADVANCE Stabilized L Ascorbic Acid Formulas

INNOVATIVE SKINCARE® has raised the bar once again in vitamin C technology with the iS CLINICAL® ADVANCE+ line. Featuring a cutting-edge vitamin C (L ascorbic acid) technology along with Copper Tripeptide Growth Factor (in select products) the ADVANCE+ line produces more rapid, pronounced improvements in the skin than ever before.

Superior Vitamin C technology:

The superior vitamin C technology employed in our remarkable ADVANCE+ formulas has been developed to increase stability and to offer time-released, continuous and steady delivery of L ascorbic acid to the cell, providing a more efficient and effective form of vitamin C. This powerhouse ingredient provides improved collagen production, exceptional antioxidant and UV-photo protection, as well as safe, natural lightening of the skin.

ADVANCE+ L Ascorbic Acid vs. Traditional L Ascorbic Acid

- Improved Antioxidant Protection: ADVANCE+ L ascorbic acid is better than traditional L ascorbic acid in its ability to squelch free radicals. On a per-molecule comparison, the number of free radicals neutralized is higher with ADVANCE+ L ascorbic acid. When both ADVANCE+ L ascorbic acid and traditional L ascorbic acid are combined with a specific number of free radicals, the traditional L ascorbic acid exhausted itself after 10 minutes. After 2 hours, ADVANCE+ L ascorbic acid was still active and neutralizing free radicals.
- Ability to be Combined With Copper: Previously incompatible, iS CLINICAL's ADVANCE+ L ascorbic acid successfully combines with copper, bringing together some of the most important elements in collagen synthesis.

Until now, the addition of copper-containing substances to vitamin C products has been quite problematic because copper oxidizes the L Ascorbic Acid. The addition of another moiety to its chemical structure allows ADVANCE+ L ascorbic acid to become much more stable and facilitates easier formulation. This is particularly important when combined with substances that might react with it. This exact issue was investigated by using copper ions as a pro-oxidant and adding it to the ADVANCE+ L ascorbic acid. The graphs below demonstrate that no negative interaction occurred between the ADVANCE+ L ascorbic acid and the copper. At the experiment's conclusion, the amount of copper and the amount of ADVANCE+ L ascorbic acid remained unchanged.



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L Ascorbic Acid and Copper Can Be Combined



Combining traditional L ascorbic acid and copper causes a chemical reaction between the 2 substances nullifying the copper and making the L ascorbic acid much less effective for the skin. This means that neither substance remains fully available for beneficial activity in the skin. Advance+ L ascorbic acid and copper, placed together in a formulation, work synergistically and do not react with each other, leaving both substances completely available to the skin.

Vitamin C is necessary for effective collagen synthesis. Copper is required as a cofactor in collagen synthesis. The unique ability of ADVANCE+ L ascorbic acid to combine with copper allows it to induce collagen synthesis much more effectively than traditional L Ascorbic Acid. Here is another set of chemical reactions (i.e. synthesis of collagen) that will potentiate each other due to their unique combination in iS CLINICAL[®] products.

Improved Collagen Production: ADVANCE+ L ascorbic acid is more effective than L ascorbic acid for inducing collagen formation. Improvement is observed in more sustained collagen production when compared with ascorbic acid. This is thought to be related to the higher cellular levels of ascorbic acid produced by ADVANCE+ L ascorbic acid. L Ascorbic acid levels at the site of action are elevated for a more extended period with ADVANCE+ L ascorbic acid than with L ascorbic acid itself.

In studies, fibroblasts from human skin were stimulated to produce collagen and then incubated in the presence of ADVANCE+ L ascorbic acid. The amount of collagen synthesized was compared to L ascorbic acid. Both types of L ascorbic acid were provided to the cells only at initiation of the experiment. With both types of L ascorbic acid, there was an immediate increase in collagen synthesis to approximately the same level. However, by the eighth day, the units of collagen production had dropped from 14 to 6 in the cells provided L ascorbic acid. In the cells provided ADVANCE+ L ascorbic acid, there was no decrease in collagen production at the eighth day.

Improved Lightening Effects: ADVANCE+ L ascorbic acid reduces the accumulation of lipofuscin induced by UVB irradiation. This has not been shown to occur with ascorbic acid. Lipofuscin is a complex of oxidation products, including oxidized lipids that are found in "age spots", the hyperpigmented areas seen with photoaging. This data suggests that ADVANCE+ L ascorbic acid is superior in ameliorating these "age spots". Furthermore, since these lesions are comprised of oxidized lipids, the research suggests that ADVANCE+ L ascorbic acid can be used to treat lipid peroxidation in general. Lipid peroxidation is involved in numerous processes associated with aging, such as vascular disease, dementia, diabetes, and others. Because all cellular membranes are comprised of lipids, this protection against lipid peroxidation provides vast positive implications for the skin.



When ADVANCE+ L ascorbic acid and traditional L ascorbic acid were each added to B16V melanoma cells to ascertain their ability to inhibit melanin production, ADVANCE+ L ascorbic acid tested superior to traditional L ascorbic acid after 1day. After 2 days, traditional L ascorbic acid had lost its effectiveness completely, while ADVANCE+ L ascorbic acid continued to decrease melanin content on day 2.

- Activity of ADVANCE+ L ascorbic acid: ADVANCE+ L ascorbic acid has pro-vitamin C activity. It is converted to L ascorbic acid within the cell. Its biologic effect, however, lasts longer than L ascorbic acid due to sustained cellular release of L ascorbic acid. This sustained activity is responsible for many of the advantages of ADVANCE+ L ascorbic acid over traditional ascorbic acid.
- Maintains Higher Ascorbic Acid Levels In Cells: Within the cell, ADVANCE+ L ascorbic acid converts to L ascorbic acid. Sustained cellular release of ascorbic acid occurs when ADVANCE+ L ascorbic acid is applied topically. ADVANCE+ L ascorbic acid is superior to L ascorbic acid in maintaining ascorbic acid levels in the cell.

Compared to traditional L ascorbic acid, efficacy is prolonged as the conversion of ADVANCE+ L ascorbic acid to L ascorbic acid proceeds within the cell at a constant rate, providing a more sustained and reliable intracellular level of L ascorbic acid.

Improved Intracellular Antioxidant Protection: ADVANCE+ L ascorbic acid is superior to L ascorbic acid in resisting oxidative degradation and higher intracellular levels of ascorbic acid are maintained for a longer period. The improved resilience of ADVANCE+ L ascorbic acid against oxidative stress is thought to be caused by the proprietary moiety to the chemical structure of the ascorbic acid.

When a colorimetric assay was used to evaluate the free radical scavenging ability of L ascorbic acid compared to ADVANCE+ L ascorbic acid, the L ascorbic acid exhausted its free radical scavenging ability after 10 minutes. The ADVANCE+ L ascorbic acid was still fully active in scavenging free radicals after 2 hours. This indicates the far superior oxidative protection provided by the ADVANCE+ L ascorbic acid.

Inhibits Melanin Production: ADVANCE+ L ascorbic acid inhibits the production of melanin.

Effects on Melanin Synthesis



Without ADVANCE+ L ascorbic acid



With ADVANCE+ L ascorbic acid

The efficacy of ADVANCE+ L ascorbic acid was tested using B16 melanoma cells treated for 12 hr with 2-O-alpha-D-glucopyranosyl-L-ascorbic acid (2.5mM) or a placebo. Following treatment theophylline (0.5mM) was added to stimulate melanin synthesis, and the cells were tested after 48 hr for the presence of DOPA quinone (a precursor to melanin) using a histochemical stain. In conclusion, ADVANCE+ L ascorbic acid acid demonstrated the ability to effectively prevent skin pigmentation.



- Helps Prevent UVB Damage: ADVANCE+ L ascorbic acid helps prevent UVB damage in human skin keratinocytes and fibroblasts. Sunburn cells are a measure of skin damage from UVB rays. They are cells that have been severely damaged by the sun and are dying, releasing toxins and inflammatory mediators. When ADVANCE+ L ascorbic acid is applied to skin before UVB exposure, the number of sunburn cells is decreased by 400% compared to the control. Furthermore, traditional L ascorbic acid allows for the production of a larger number of sunburn cells caused by UVB exposure than does ADVANCE+ L ascorbic acid.
- Promotes Production Of HGF: ADVANCE+ L ascorbic acid promotes the production of HGF. HGF (Hepatocyte Growth Factor) is the growth factor that induces growth and development of all epithelial, cell types including skin. Measured basal HGF production by human skin fibroblasts increases with the addition of ADVANCE+ L ascorbic acid.
- Protects Against Lipid Peroxidation: ADVANCE+ L ascorbic acid protects against lipid peroxidation in the presence of vitamin E. When human keratinocytes were irradiated with UVB, the intracellular amount of peroxidized lipids doubled. If, prior to UVB irradiation, ADVANCE+ L ascorbic acid was added to the human keratinocytes, much less lipid peroxidation occurred.
- Potentiates Vitamin E: ADVANCE+ L ascorbic acid potentiates the function of vitamin E and vitamin E's antioxidant ability. When human keratinocytes were irradiated with UVB, adding ADVANCE+ L ascorbic acid and vitamin E completely protected the cells, i.e. the amount of damage was the same as without any radiation. This highly significant finding illustrates the power of the ADVANCE+ line in potentiating effects of other antioxidants. ADVANCE+ L ascorbic acid and vitamin E are a particularly good combination as together they give synergistic antioxidant protection to aqueous-soluble elements (within the cell and between cells) and to all lipid (fat) soluble elements (cell membranes enclosing the cell and its organelles to maintain their integrity).
- Increases Antibody Production and Stimulates Immune Function: ADVANCE+ L ascorbic acid is a potent stimulator of immune function and antibody production in humans.

Both ADVANCE+ L ascorbic acid and traditional L ascorbic acid are stimulators of immune function. Antibody production by peripheral lymphocytes was examined when the lymphocytes were stimulated with pokeweed mitogen or Staph aureus. ADVANCE+ L ascorbic acid and the L Ascorbic Acid induced equivalent amounts of antibody production.

Encourages Proliferation of Fibroblasts and Increases Collagen Production: ADVANCE+ L ascorbic acid assists proliferation of human skin fibroblasts and collagen production.

Effects on Collagen Synthesis



Absorption of ADVANCE+ L Ascorbic Acid

ADVANCE+ L ascorbic acid is well absorbed through intact skin. When applied topically, granules of ascorbic acid are shown microscopically within the skin. This illustrates that the ADVANCE+ L ascorbic acid is absorbed.



Placebo (containing NO source of L-Ascorbic Acid and NO ADVANCE+ L-Ascorbic Acid) was applied to a human forearm, covered with occlusive film for 12 hours, the film removed and the skin biopsied after 24 hrs.

L-Ascorbic Acid granules found normally in skin are stained by the special silver stain.



ADVANCE+ L-Ascorbic Acid was applied to a human forearm and the same experiment was completed. Numerous granules of L-Ascorbic Acid was absorbed quite well. Furthermore, this experiment illustrates that ADVANCE+ L-Ascorbic Acid was converted to L-Ascorbic Acid within the skin cells.

Natural Occurrence of ADVANCE+ L Ascorbic Acid ADVANCE+ L ascorbic acid is found in vivo in mammals, within all cells of their bodies, throughout their lives. In plants, it is found in the fruit of Lycium barbarum.



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PRO-HEAL® SERUM ADVANCE+

PRO-HEAL[™] SERUM ADVANCE+ features our ADVANCE+ L ascorbic acid, along with a more refined form of olive leaf extract and bioflavonoids. These superior ingredients are combined with vitamin E, vitamin A, Arbutin, and mushroom extract. PRO-HEAL[™] SERUM ADVANCE+ exhibits the following properties:

Provides Our Highest Level Of Antioxidant Protection: PRO-HEAL[®] SERUM ADVANCE+ is clinically proven to offer more antioxidant protection than ever before.



Comparative Antioxidant Strength

ORAC (Oxygen Radical Absorption Capacity) measures total lipophilic and hydrophilic antioxidant capacity Testing independently performed by Brunswick Labs.

Offers Remarkable Healing Properties: PRO-HEAL® SERUM ADVANCE+ has been clinically proven to effectively protect the skin against inflammation caused by an applied agent. Due to this characteristic, this formulation has potential applications for all types of inflammatory conditions including environmental exposures, solar damage, aging and wrinkling, procedures, etc.

Inflammation can be induced in human skin by any of the stressors mentioned above or experimentally by exposing skin to a strong detergent with occlusion. Human skin was repeatedly exposed in vivo to a strong detergent for 48 hours. On one side, PRO-HEAL® SERUM ADVANCE+ was applied immediately prior to detergent application. On the opposite side, no product was applied. This side served as a control. A cumulative inflammation score was given by an examiner and included the parameters of erythema, roughness, scaling, edema and fissure formation. The highest possible score of inflammation was +20. On the side treated with PRO-HEAL® SERUM ADVANCE+, the cumulative inflammation score was +1 after 48 hours. On the untreated control side, the cumulative inflammation score after 48 hours was +11. Application of PRO-HEAL® SERUM ADVANCE+ provided near-complete protection against inflammatory damage caused by an applied strong detergent. A table of the cumulative inflammation score is shown below:



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PRO-HEAL® ADVANCE+ Clinician's Inflammation Score Chart

PARAMETER	CONTROL (no PRO-HEAL® SERUM ADVANCE+)	TREATED (with PRO-HEAL® SERUM ADVANCE+)
Erythema (0 - ⁺ 4)	+3	+1
Roughness (0 - ⁺ 4)	+2	0
Scaling (0 -*4)	+3	0
Edema (0 - *4)	+1	0
Fissure Formation (0 -*4)	+2	0
Cumulative Score (0 -*20)	+11	+1

Biopsies were performed on the same subject in the experiment above in which a strong detergent was applied. Photomicrographs of the control side and side pretreated with PRO-HEAL® SERUM ADVANCE+ are shown below. These are both H and E stains of full-thickness skin biopsies. The control side shows marked inflammation with migration of lymphocytes and Langerhans cells into the area, edema and destruction of normal skin architecture. On the side treated with PRO-HEAL® SERUM ADVANCE+, inflammatory cells are conspicuously absent and normal skin architecture is preserved.

Effects on Inflammation



High power: Time: 48hrs - H & E stain control Control - no product applied

Note the marked inflammation with migration of lymphocytes and Langerhans cells into the area. Edema occurs and normal skin architecture is lost.



High power: Time: 48hrs - H & E stain with PRO-HEAL® SERUM ADVANCE+ Note the absence of inflammatory cells and preservation of normal skin architecture.

Dermatopathology independently performed by PAML/InCyte

In this study, inflammation was induced by an applied agent. No product was applied to the control side. PRO-HEAL® SERUM ADVANCE+ was applied to the treated side. Both treated and untreated sides were biopsied. The biopsies show the amazing protective ability of PRO-HEAL® SERUM ADVANCE+ against inflammation.



References available upon request.

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PRO-HEAL[®] SERUM ADVANCE+[®]

3.1 pH +/- 0.5 15ml, £59 30ml, £104

REPARATIVE | HEALING | PROTECTIVE

PRO-HEAL® SERUM ADVANCE+ features our scientifically-advanced vitamin C time release technology, combined with a superior form of olive leaf extract, and pure vitamins E and A. This powerful formulation significantly increases antioxidant protection and offers enhanced healing properties. A clinically-proven formula, PRO-HEAL® SERUM ADVANCE+ is excellent for treating rosacea, cystic acne, insect bites and some forms of dermatitis.

BENEFITS

- Heals & Reduces inflammation
- · Provides UV Photo protection
- · Offers soothing relief from insect bites & dermatitis

PRODUCT HIGHLIGHTS

"I don't like anything heavy on my face, especially at night because I want my skin to breathe. I interchange three iS Clinical serums, depending on how my skin is feeling: Proheal Serum, Advance+ to treat inflammation; Hydra-Cool Serum with hyaluronic acid for dehydration; and Active Serum with glycolic, kojic, lactic, and salicylic acids, to exfoliate and boost radiance.'

Mamie McDonald, Celebrity Facialist to Beyonce, Chloe Sevigny, Eva Mendes and Jay-Z.

CLINICALLY PROVEN TO REDUCE ERYTHEMA & INFLAMMATION		
Control	With PRO-HEAL SERUM ADVANCE+	
48hrs I H&E Stain Note the marked inflammation with migration of lymphocytes and Langerhans cells into the area.	48hrs I H&E Stain Note the absence of inflammatory cells and preservation of normal skin architecture.	
and normal skin architecture is lost.		

KEY INGREDIENTS	INGREDIENT BENEFITS
ASCORBIC ACID (vitamin C) 15.0%	Scientifically-advanced, stabilized form of L ascorbic acid providing time-released, continuous delivery. Potent antioxidant with photo-protective and anti-inflammatory properties. Stimulates collagen synthesis and promotes wound healing.
TOCOPHEROL (vitamin E) 1.0%	Potent antioxident that inhibits DNA damage, thymine dimer formation, inflammation and oxidative damage. Protects against UV-induced (photo) damage.
RETINOL (vitamin A) 1.0%	Natural vitamin A that functions as a powerful antioxidant with potent free radical scavenging ability, improves collagen synthesis by favouring biosynthetic activity of fibroblasts, and promotes wound healing.
OLEA EUROPAEA (OLIVE) LEAF EXTRACT 0.5%	Potent, natural antibiotic, anti-acneic, anti-inflammatory, and antioxidant. Also has properties that fight skin damage from intrinsic aging, solar radiation, and any tissue injured by any mechanism.
POLYPORUS UMBELLATUS (MUSHROOM) EXTRACT (source of kojic acid) 0.5%	Inhibits tyrosinase enzymes that produce melanin, thus controlling hyperpigmentation. Also exhibits powerful antibacterial, antimicrobial, and antibiotic properties.
ZINC SULFATE 0.5%	Antioxidant that provides photo-protection, enhances wound healing, improves immune function, and decreases cancer risk. Possesses anti-inflammatory properties.
ARBUTIN 0.5%	Inhibits tyrosinase enzymes that produce melanin, thus controlling hyperpigmentation.

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