



# MEDCO FORUM<sup>®</sup>

PRESENTING INNOVATIVE PRODUCTS AND SERVICES TO HEALTHCARE PROFESSIONALS

VOLUME 16 NUMBER 5

MARCH 2009

REPRINT

## VITAPHENOL<sup>®</sup> SKIN CARE COLLECTION

*An Evolution in Skin Care*

When a cosmetic surgeon renowned for his pioneering research of multiple laser techniques and skin rejuvenation teams up with the award-winning founder of a highly successful skin care company, then the outcome of their collaboration is sure to attract great interest. And this is exactly what happened when Mitchel Goldman, MD and Diane York-Goldman developed the **Vitaphenol<sup>®</sup> Skin Care Collection** available exclusively through physicians and physician-affiliated centers by **Avidas Pharmaceuticals (Doylestown, PA)**.

The reason for such interest is that both women and men are taking greater preventative action towards combating the aging process. This mega-trend can now be extended to the human body's largest organ—the skin, your own personal home.

"Skin is attacked by free radicals caused by pollution, sun and daily environmental stress" says Charles Pamplin III MD, Chief Medical Advisor for Avidas. "When used as directed, Vitaphenol frees the skin to repair, protect and visibly anti-age itself." So what does Vitaphenol contain to make it so effective and are such claims supported by clinical studies?

The foundation of the **Vitaphenol Skin Care Collection** is the Vitaphenol Complex, a unique combination of highly potent, medically-compounded anti-oxidants that includes:

- **Mangosteen** (*Garcinia mangostana*) a newly discovered powerhouse with a high level of xanthones, which have been found to have greater anti-oxidant properties than vitamins E or C.
- **Pomegranate** (*Punica granatum*) another high potent anti-oxidant with known topical benefits.
- **Green and white teas** (*Camellia sinensis*) which contain polyphenols, and whose fundamental properties have long been established.

The cornerstone of the Vitaphenol treatment regimen is the Vitaphenol Cellstructure Rejuvenating



*Mangosteen (*Garcinia mangostana*) is a newly discovered powerhouse with a high level of xanthones, which have been found to have greater anti-oxidant properties than vitamins E or C.*

Serum (CRS). This clinically-proven serum includes the Vitaphenol Complex with additional state-of-the-art ingredients, such as the recombinant growth factor, TGF- $\beta_1$  (transforming growth factor- $\beta_1$ ), highly stabilized 7.5 percent L-ascorbic acid and black cohosh (*Cimicifuga racemosa*) extract.

So how can the claims for this product line be substantiated, especially when there seem to be so many other anti-aging products? One way to validate the attributes of products is data generated from clinical trials.

Hsu *et al.*<sup>1</sup> evaluated treatment for improving facial features with a mixture of topical anti-oxidants (Vitaphenol) as an alternative to laser and cosmetic resurfacing. The latter procedures have some inherent disadvantages, place the patient at risk for complications and may not be widely accessible to the general population.

The study evaluated the efficacy and tolerability of Vitaphenol compared to a placebo cream in rejuvenating facial skin. Each subject was instructed to apply either Vitaphenol Skin Cream or placebo cream to a randomized half of their face on a twice-daily basis for a total of 60 days. Subjects were

blinded to which side of the face was receiving the active investigational cream and evaluated at baseline, 30 and 60 days: objectively, by a blinded board-certified dermatologist who attributed a Rao-Goldman Facial Wrinkling Score (1 to 5) to both the right and left sides of the subjects's face; and subjectively, by asking the participants to make their assessment, based on a standard set of questions.

After the short study period of 60 days, results showed that, overall:

- 41 percent of study subjects preferred the results of Vitaphenol while only 0.06 percent favored the placebo.

For the Vitaphenol treated areas:

- 29 percent had a visible difference in skin texture;
- 27 percent had a decrease in fine lines and wrinkles;
- 24 percent experienced improvement in skin elasticity;
- 18 percent experienced an increase in skin hydration.

The authors admit that one criticism of the study is that the placebo cream is not entirely "inactive" since some of the components may have some beneficial attributes. But what is clear, however, is that the addition of the anti-oxidants found in Vitaphenol had an additive effect to enhance the improvement of age related changes in the skin.

Transforming growth factor- $\beta_1$  (TGF- $\beta_1$ ) found in Cellustructure Rejuvenating Serum is known to directly cause the expression of extra-cellular matrix components collagen, elastin and proteoglycans. Ehrlich *et al.*<sup>2</sup> compared the effects of CRS containing recombinant, liposomal encapsulated TGF- $\beta_1$ , L-ascorbic acid, stabilized using a proprietary



*Vitaphenol Cellustructure Rejuvenating Serum from Avidas Pharmaceuticals.*

polymer matrix technology and *Cimicifuga racemosa* extract with Vitamin C and Skinmedica® Tissue Nutrient Solution Recovery Complex (TNS), an early generation growth factor-based product.

In the first arm of the study, 12 subjects were randomized to apply CRS to the left or right side of the face and a cream containing L-ascorbic acid and *C. racemosa* in silicone base (vitamin C [Vit C]) to the contralateral side twice daily for three months. In the second arm of the study, 20 subjects were randomized to apply CRS to the left or right side of their face and Tissue Nutrient Solution Recovery Complex (TNS) to the contralateral side of their face twice daily for three months. Digital photographs were scored by study-blinded physicians and self-assessments were completed by all subjects at baseline and at the conclusion of the study.

Results indicated that CRS and TNS were well-tolerated, and all subjects completed the three-month protocol for the CRS versus the Vit C arm of the study. Physicians rated success in facial wrinkling scores for 27 of the 31 subjects. On average, responders showed a 21.7 percent improvement in physician-rated wrinkle scores; and 18 of 31 (58 percent) reported a noticeable improvement

on their CRS-treated side. Both CRS and TNS demonstrated significant success between baseline and three-month scores, and both were superior to Vit C. But patients expressed a high preference for CRS over TNS.

Part of this may be attributed to the liposomal encapsulation of TGF- $\beta_1$  which protects the growth factor protein from degradation. Older growth factor products such as TNS lack this protection and results in the degradation of growth factor proteins once they come into contact with the skin, giving off a characteristic and unpleasant odor. The authors concluded that CRS was effective in minimizing the appearance of facial rhytides, and they attributed this success to the incorporation of TGF- $\beta_1$ .

Mitchel Goldman, MD is very enthusiastic about the results of these studies. He comments that the Vitaphenol product line is unique in having evidence-based data through clinical studies, whose results have been published in peer-reviewed literature. "This emphasizes that the efficacy of the Vitaphenol product line has been demonstrated in a double-blind scientific study, which is very important," adds Dr Goldman. That the **Vitaphenol® Skin Care Collection** has withstood such scrutiny speaks to the quality of the product line. ♦

#### To Learn More

For more information about the Vitaphenol Skin Care Collection, please call **Avidas Pharmaceuticals** at 1-877-970-3376, or visit the company's Web site at [www.vitaphenol.com](http://www.vitaphenol.com).

*VITAPHENOL® is a registered United States trademark of La Jolla Spa MD Inc.*

#### References:

1. Hsu, J., Skover, G. & Goldman, M.P. *J Drugs Dermatol* 2007 6(11) 1141-48.
2. Ehrlich, M., Rao, J., Pabby, A. & Goldman, M.P. *Dermatological Surgery* 2006 32(5) 618-625.