

TERSUS LIFE SCIENCES

C16:1n7 PALMITOLEATE
VISION-DES®
HYDROTEARS



Supports & Maintains

- Advanced Dry Eye Relief
- Reduced Tear Evaporation
- Improved Tear Lipid Quality and Lubrication

METABOLIC DIETARY
SUPPLEMENT

Tersus Life Sciences LLC

8000 Health Center Blvd., STE 100, Bonita Springs, FL 34135 Phone: 239.390.1226 tersus@tersuspharma.com

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Tersus Life Sciences' mission is to drive scientific progress in ocular health with evidenced based science and claims substantiation by pre-clinical and clinical research

Vision-DES® *HydroTears is a breakthrough oral dose softgel of highly purified mono-unsaturated palmitoleic acid that targets dry eye causes and symptoms.*

DES - Dry Eye Syndrome

The most important goals of DES treatment are to reduce or alleviate signs and symptoms; maintain visual function; reduce or prevent structural damage; and most important to prevent progression. These can be achieved by increasing the number of functional meibomian glands producing better quality tears, with higher lipid content and reducing the rate of partial blinks which will lead to increased tear production, reduced tear evaporation and improved tear quality.

Most prescription drug therapies for dry eye syndrome are expensive and require continued use of sometimes twice daily applications to be effective. Three out of five prescription dry eye therapies may not be recommended for pregnant or nursing mothers.

Overall the treatment options available to date are either not satisfactory or can only be used short term or are very uncomfortable and take long to have a satisfactory effect. More important, combination treatments are most often required in order to address greater complexity of symptoms associated with DES.

Vision-DES® containing Provinal® works with your body naturally to help reduce inflammation, improve blink response, tear break up time and better quality of tears. The strongest and most undisputable testimonial in favor of Vision-DES's effectiveness is clearly the patients' ever growing demand for a continued supply of the supplement even after the conclusion of the Tersus Life Sciences sponsored clinical trials.

Nature's Inflammation Modulator Target: Dry Eye Syndrome

What if the most powerful modulator of inflammation in the human body was the least well-known?

No, it's not omega-3, EPA/DHA. No, it's not DPA.
It's actually omega-7 (palmitoleic acid)

What is POA / Palmitoleic Acid?

Palmitoleic acid is a member of the class called omega-7 fatty acids. Omega-7's include several different fatty acids. For the purposes of this discussion, when we refer to omega-7, we're referring to POA, short for palmitoleic acid.

Unlike the better known polyunsaturated omega-3's, omega-7's are monounsaturated fats while omega-3 fatty acids are beneficial largely because they become incorporated into anti-inflammatory molecules, omega-7 or POA has an entirely different mechanism of action.

POA functions as a signaling molecule that facilitates communication between fat and muscle tissue in your body. This special signaling function qualifies POA to be identified as a unique lipokine—a hormone-like molecule that links distant body tissues to assure optimal energy utilization and storage.

That's what allows POA to have broad-reaching effects in the body.

POA and Ocular Health

Dry eye results from reduced tear production, excessive tear evaporation or abnormal tear composition. The tear film of the eye consists of aqueous, mucous, and lipid components. A healthy tear film relies on a synergistic interaction of the lacrimal glands, eyelids, and functional meibomian glands. Dysfunction of any component can lead to dry eye disease. The most common risk factors for DES are age, female gender, contact lens wear, hormonal changes (primarily due to decreased androgen) and commonly used systemic medications such as antihistamines and selective serotonin receptor antagonists amongst others. Vision-DES® has shown in studies to:

- Help your eyes produce more of your own natural tears
- Improve tear lipid quality and lubrication
- 4.7 Times more effective than Omega-3

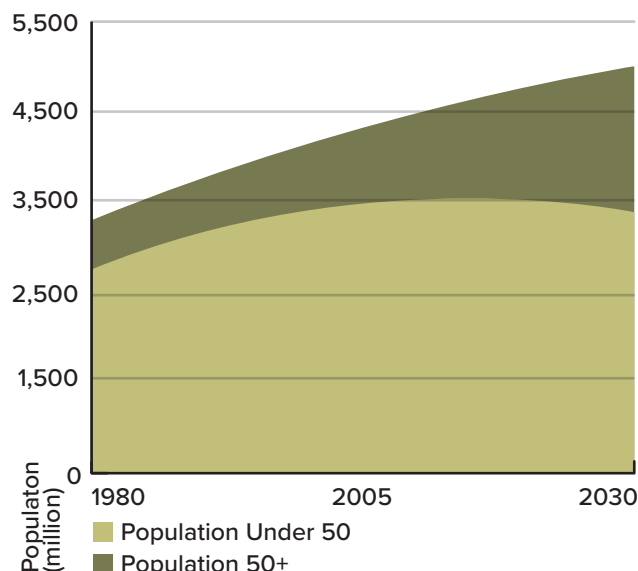


Two Key Factors Driving Dry Eye Market Trends

Growing Aging Population

By 2030, G20 Nations' 50+ population will represent 35% of the total population

Population of G20 Nations by Age 1980 - 2030

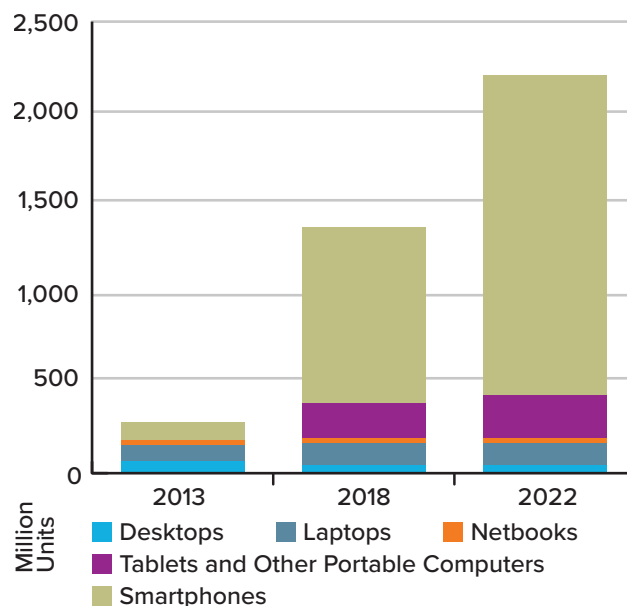


Source: 2018 Euromonitor Trends and Developments in the Global Eye Care Market

Modern Lifestyle Factors

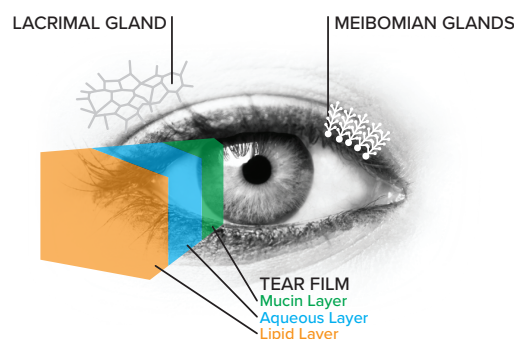
Among the greatest lifestyle factors contributing to dry eye is the increase in exposure to digital screens

Global Volume Sales of Computers & Smartphones 2013/2018/2022

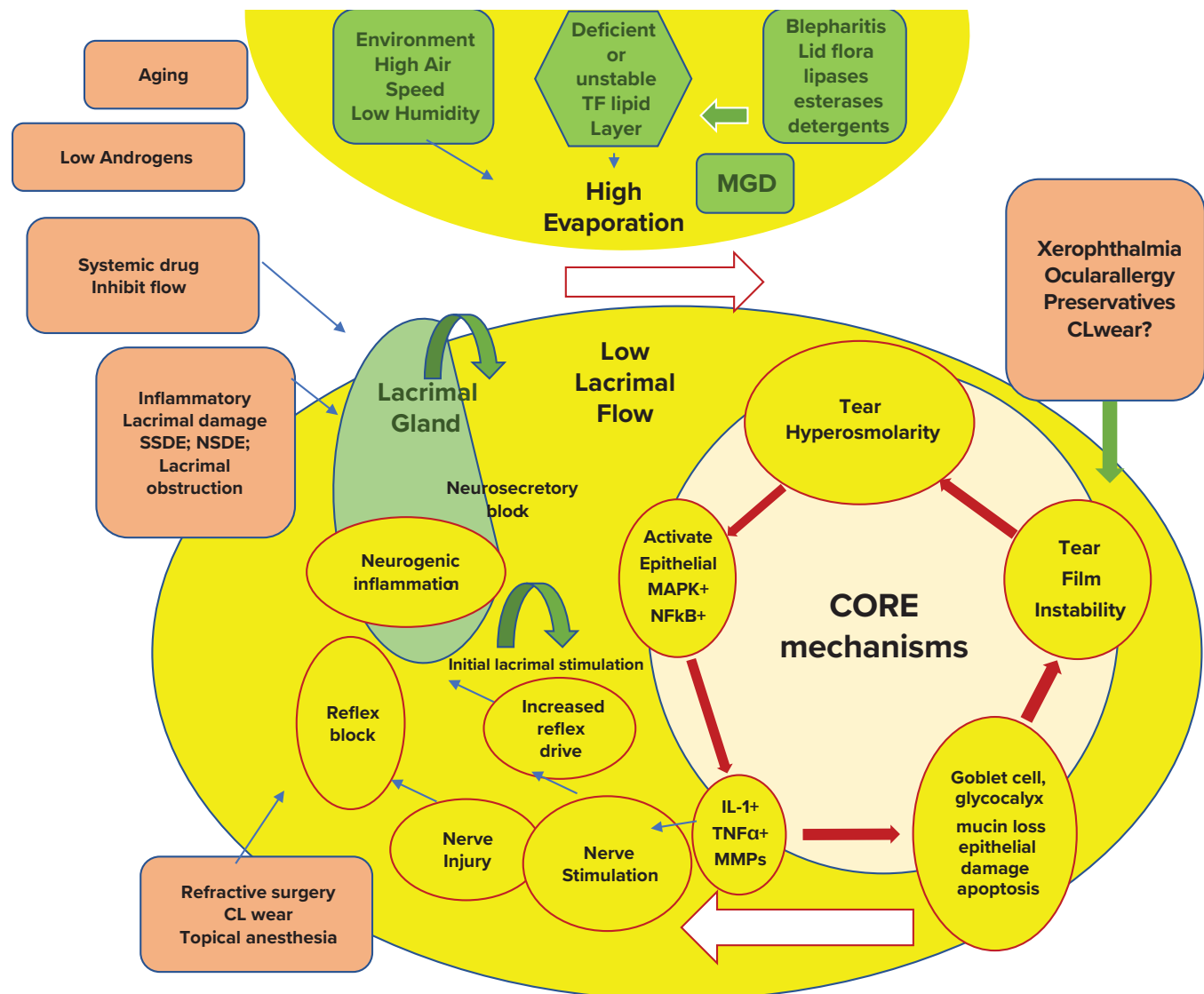


Tear Fluid Formation

- Tears have three basic compositions – oil as a lubricant, aqueous fluid and mucous. The aqueous fluid moves across your eyes as you blink and is mixed with oil from your meibomian glands to form your tears. The oil film produced by small glands on the distal ends of the eyelids, meibomian glands can become blocked and incapable of secreting and distributing healthy nourishing tears.
- Dry Eye Syndrome (DES) is a multifactorial condition of the tears and ocular surface that can result in ocular discomfort and visual impairment.
- While it is estimated that 17.9% of men and 10.5% of women suffer from symptoms, the percentage in people older than 50 years of age climbs to 30%.
- DES presently represents a continuously more frequent reason for ophthalmologic consultation due to ocular discomfort that commonly leads to problems with sustained daily visual activities like reading, using a computer, driving at night and carrying out professional work.



Dry Eye Pathophysiology



- The lacrimal gland, meibomian gland, and ocular surface inflammation play a significant role in DES.
- Patients with DES have an increased concentration of inflammatory cytokines, such as interleukin-1, interleukin-6, and tumor necrosis factor alpha, in the tear film.
- Once excessive inflammation takes hold, it can lead to a vicious cycle: effector T cells secrete more pro-inflammatory cytokines into the tear film, recruiting more effector T cells and stimulating still greater inflammation, causing changes in tear production, quantity and/or quality.
- Over time, this can damage the ocular surface and the tear-secreting glands, making dry eye worse. Thus, inflammation is both a cause and a result of damage to the ocular surface.

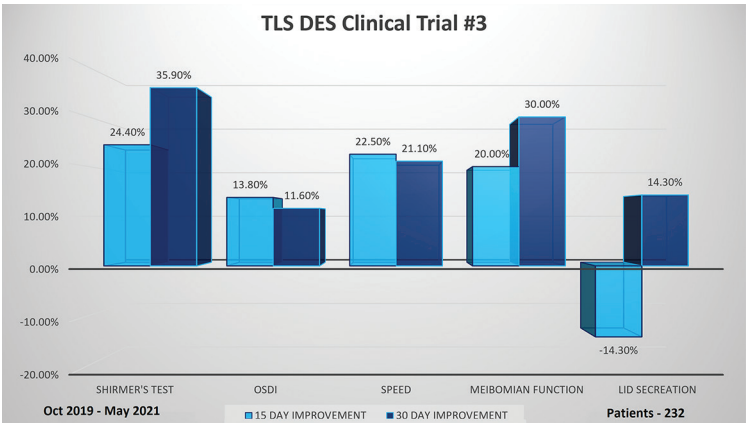
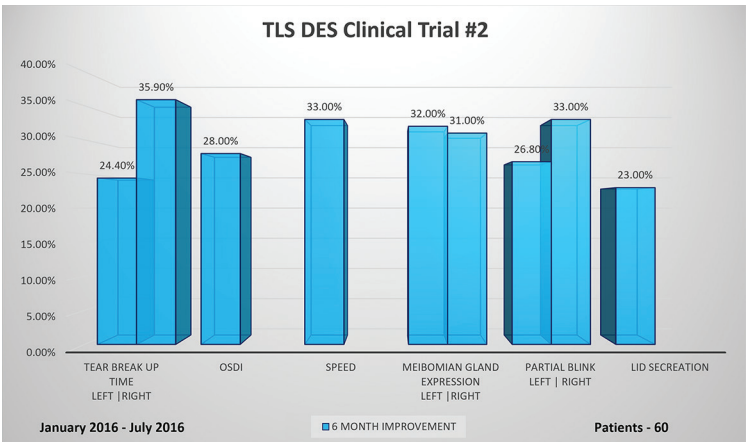
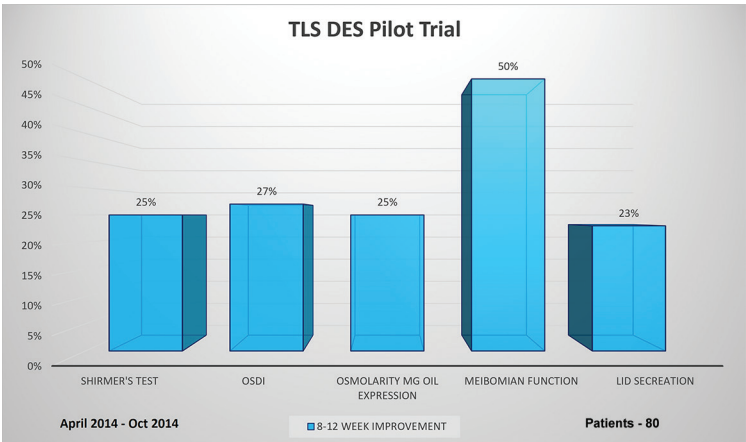
Tersus Life Sciences Human Clinical Trials on DES

The results of the present studies conducted with Vision-DES® suggest that there is significant clinical benefit to patients from oral supplementation with highly concentrated Palmitoleic acid, especially patients suffering from evaporative dry eye disease. Six months of continuous supplementation with Provinal® POA achieved a significant relief from the symptoms of dry eye syndrome and a high level of patient satisfaction as measured by the SPEED score.

The most important goals of DES treatment are to reduce or alleviate signs and symptoms; maintain visual function; reduce or prevent structural damage; and most important to prevent progression. These can be achieved by increasing the number of functional meibomian glands producing better quality tears, with higher lipid content and reducing the rate of partial blinks which will lead to increased tear production, reduced tear evaporation and improved tear quality.

The noteworthy improvements of dry eye symptoms experienced by the patients on Vision-DES® are clearly explained by the study findings. A clinically significant increase of functioning Meibomian glands with healthy oil expression, was observed in both eyes. Increased healthy meibomian gland function leads to better quality tear production with healthy oil expression and reduced tear evaporation, improving two of the most important causes but also the most bothersome symptoms of DES.

Furthermore, patients treated with Vision-DES® showed a substantial reduction of tear evaporation and improved visual acuity which are the results of improved tear break-up time with increased stability of the tear film and more complete blinks.



Vision-DES® Clinical Support

- An open label proof-of-concept study evaluated the effects Vision-DES® on dry eye syndrome (DES) on sixty patients.
- The primary objective was to evaluate the effects of palmitoleic acid administered daily over a 90 and 180 day period on the clinical management of dry eye syndrome caused by Meibomian Gland Dysfunction (MGD).
- Study results after three and six months treatment with 420 mg Vision-DES®, providing 210 mg palmitoleic acid, showed a significant improvement in Meibomian Gland function.

Overall, there was a statistically significant reduction by 33% ($p=0.0002$) in the severity of symptoms as measured by the Standard Patient Evaluation of Eye Dryness (SPEED) score, partial blink was improved by 33% (p -value 0.0045) and 27% (p -value 0.0082) in the right and left eye respectively and tear break-up time (TBUT) was increased by 42% (p -value 0.0001) and 39% (p -value 0.0001 respectively for the right and left eye.

“

Study results after three and six months treatment with 420 mg Vision-DES®, providing 210 mg palmitoleic acid, showed a significant improvement in Meibomian Gland function.

”

The results of these studies have shown that the systemic use of Vision-DES® with Provinal® over a six-month period presented the following significant advantages:

- Patient satisfaction with the fast and effective alleviation of previous dry eye problems without adverse reactions
- Increased patient compliance due to the very favorable dosage form
- Significant improvement of overall DES symptoms including:
 - o Increased number of functioning Meibomian glands with healthy oil expression
 - o Production of better quality tears, higher lipid content and reduced tear evaporation
 - o Increased stability of tear film
 - o Improvement in blinking (more complete blinks with proper spreading of tear film)
 - o More hygienic anatomical presentation of eyelid margins around gland orifices.

“

The results of these studies clearly suggest that highly concentrated palmitoleic acid nearly void of palmitic acid (Vision-DES®) may be a safe and effective alternative for the management of dry eye syndrome.

”

Observational Study

An observational study was conducted to assess the effect of Provinal® POA on 80 patients with evaporative dry eye disease (i.e. dry eye disease) over 11 months. The results were that, of the 80 patients, 74 experienced positive effects. Improved comfort was noted within 7-14 days, and improvements in osmolarity, symmetry binocularly and MGD (grade 2) was noted within 30 days. Within 60-90 days there were improvements in MGD (grade 3-4), with >50% improvement among all patients with MGD grade 4. Within 6 months there was positive Meibum production for all of the 74 patients.

“ The results were that, of the 80 patients, 74 experienced positive effects. Improved comfort was noted within 7-14 days, and improvements in osmolarity, symmetry binocularly and MGD (grade 2) was noted within 30 days. ”

This is likely the most important clinical observation as it can consistently be measured regardless of environmental factors and provides the best consistency in measurements among practitioners. Patients who discontinued omega-7, typically due to running out of the supplement, noticed a return of symptoms within the week. Additionally, patients were found to be very compliant and appreciate not only improved eye comfort but also generally reported feeling healthy. Patients’ experience included: no side effects, no watery eyes, no need to wake up in the night to put drops in my eyes, overall generally felt healthier, and decreased redness. Among the 6 patients who did not experience positive effects, the proposed reason for failure included surgery (Lasik), behavior (OCD) and mechanical (lid wiper epitheliopathy Sjogrens).

Market, Causes & Symptoms Of Dry Eyes

The Dry Eye Syndrome Market is expected to report strong growth (7% CAGR) between 2016 – 2024 Incidence levels continue to rise, driven by various environmental and physiological causal factors.

CAUSES	SYMPTOMS
<ul style="list-style-type: none">• Age > 55 years• Extensive use of smart devices• Contact lenses• Laser eye surgery• Cigarette smoke and other air pollutants• Air conditioning• Incomplete blinking• Certain disease states	<ul style="list-style-type: none">• Redness• Stinging• Itching• Foreign body sensation• Light sensitivity• Blurred vision• Incomplete blinking

Vision-DES® HydroTears Mechanism of Action in Dry Eye

The potential anti-inflammatory mechanism of palmitoleic acid is believed to result from the reduction of mRNA levels of pro-inflammatory adipocytokines, liver levels of interleukin (IL)1- β and IL-12, and IL-8, tumor necrosis factor (TNF)- α , TLR4, and increase of IL-1Ra mRNA expression which inhibits the pro-inflammatory effects of IL1- β .

The noteworthy improvement of dry eye symptoms experienced by patients on Vision-DES® are clearly explained by a clinically significant increase of functioning Meibomian glands with healthy oil expression, was observed in both eyes.

Increased healthy meibomian gland function leads to better quality tear production with healthy oil expression and reduced tear evaporation, improving two of the most important causes but also the most bothersome symptoms of DES.

Furthermore, patients treated with Vision-DES® showed a substantial reduction of tear evaporation and improved visual acuity which are the results of improved tear break-up time with increased stability of the tear film and more complete blinks.

Purified POA Benefits in Dry Eye

Reduced Severity of Dry Eye Symptoms

- 33% (p=0.0002) in the severity of symptoms as measured by the Standard Patient Evaluation of Eye Dryness (SPEED) score.

Improved Blink Response

- Partial blink was improved by 33% (p-value 0.0045) and 27% (p-value 0.0082) in the right and left eye respectively.
- A complete or proper blink is one in which the upper eyelid meets the lower eyelid. This physical connection is what causes the glands to be “squeezed” and the tear film released. Incomplete blinking may temporarily relieve the eye from dryness, but fails to nourish the eye. Over time, this can cause redness, dryness, itchiness, and ultimately gland dysfunction and Dry Eye Disease.

Tear Break-up Time (TBUT)

- Increased by 42% (p-value 0.0001)
- Tear break-up time (TBUT) is determined by measuring the interval between instillation of topical fluorescein 0.5% and appearance of the first dry spots on the cornea.



Tersus Life Sciences
THE OMEGA-7 COMPANY

**Contact us for a quote or to learn more about our clinical research on Vision-DES®,
it's unique properties and why it should be in your products!**

239-390-1226 or tersus@tersuspharma.com



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