

## New drops, nutritional supplement help combat dry eye

Artificial tears, eye drops and an all-natural oral supplement are leading the new crop of treatments.

Dry eye is an age-old affliction, and researchers are constantly developing new treatments to help combat it. Rather than duplicating products already on the market, many companies are searching for new ways to get to the root of the dryness and treat the underlying cause. Today's dry eye treatment drops, and even a nutritional supplement, are designed to restore function of the oil-secreting and mucin glands as well as help the cornea retain moisture.

### Inspire's new drop

Inspire Pharmaceuticals (Durham, N.C.) dry eye drop, INS365, is currently in phase 3 clinical trials. Upon instillation, the agent binds to the P2Y2 receptor in the eye cells, which triggers a number of events, said Christy Shaffer, president and CEO of Inspire.

"It stimulates the release of a lubricating substance on the surface of the eye called mucin, and it also stimulates natural tearing," she told *Primary Care Optometry News*. "Additionally, the tears are composed of normal constituents, so it allows the patients to have their natural tearing mechanism increased as well as the lubricating mucin substance increased. It is essentially turning on the natural protective and cleansing mechanism of the eye. It's a pharmacological, receptor-based approach to the disease, as opposed to artificial tears that temporarily provide some moisture or lubrication to the surface."

Results of the phase 2 study, which included 150 patients over a 4- to 6-week period, showed very good safety and tolerability of the product, said Dr. Shaffer, with no burning or stinging sensation upon instillation.

"We were able to demonstrate statistically significant improvements in corneal staining, which is one of the most important objective measures for the treatment of dry eye," she said. "We also saw strong trends in improvement in various symptoms of dry eye, including itching, burning and pain in this dose-ranging trial. We had quite a few elderly patients and a number were postmenopausal women."

The phase 3 study is examining approximately 1,000 patients at 60 eye care centers across the country. The company hopes to complete the studies by 2002, file the new drug application (NDA) by the end of that year and launch the product in 2003, Ms. Shaffer said.

### Tears Naturale Forte

Alcon (Fort Worth, Texas) launched its new dry eye therapy, Tears Naturale Forte, on March 5. Kim Douglas, product manager for Alcon, said that the new product takes the "DuaSorb" feature of Tears Naturale II a step further with its new technology, TriSorb.

"TriSorb is a combination of hydroxypropylmethylcellulose (HPMC), Dextran 70 and glycerin," she said. "The unique combination of the three demulcents reduces vapor pressure, which, in turn, retains moisture and slows evaporation like no single demulcent can."

Another unique feature of Tears Naturale Forte is a surface tension that is closer to the natural tear, said Ms. Douglas.

"That will give a better corneal wettability and minimal disruption of the tear film," she said.

### Products in the pipeline at Novartis

While Novartis Ophthalmics (formerly CIBA Vision, Duluth, Ga.) has dry eye products in the pipeline as the result of a new alignment with Pharma, none have been made public yet, said George Minno, PhD.

"We're exploring some new products with other organizations; however, we're not at liberty to discuss them at this time," he said.

At the SECO meeting in February, Dr. Minno spoke about an androgen therapy being developed by David Sullivan at Harvard University. "His work has shown that restoration of the lacrimal glands improves dry eye," he said.

As far as the future of dry eye, Dr. Minno said that the industry is waiting for prescription treatments to be approved.

"The only thing we have on the market now are over-the-counter products," he said. "As some of the products in development reach the market, they will satisfy needs that aren't currently met."

### **A nutritional supplement for dry eye**

ScienceBased Health (Corte Madera, Calif.) has developed a nutritional supplement, HydroEye, that focuses on the deficiency of normal lipids and mucinous components. Each capsule is a formulation of black currant seed oil, pyridoxal 5-phosphate, vitamin C, vitamin A, mucin complex and magnesium, which helps address the factors causing dry eye and support natural tear formation, said Spencer Thornton, MD, medical advisor to ScienceBased Health.

"This is the first time that a balanced formula, combining the components necessary to restore function of the oil-secreting and mucin glands, has been available to the public through optometrists and ophthalmologists," he said.

"I hear success stories every day from doctors with patients who did not respond to any drops, punctum plugs or any other form of treatment."

Dr. Thornton said that no adverse reactions have been reported with HydroEye.

"Additionally, there have been no reports of interactions with most of the pharmaceuticals used to treat rheumatoid arthritis, hypertension and other conditions that can be related to dry eye," he said. "It seems to be both safe and effective."

He recommends taking one capsule twice a day or more, depending on the severity of the dryness. Efficacy does not seem to be affected by ingestion either with or without food, he said. Dr. Thornton added that patient experience with response time seems to vary.

"I've heard several patients say they can see results in the first 2 weeks, and others say it takes 2 months," he said. "I think it depends on the underlying cause of the dry eye."

### **Other treatments**

Additional studies are being performed on Restasis (cyclosporine), said Allergan director of media and investor relations Suki Shattuck.

"We're in the process of finalizing the protocols for a confirmatory study, and we'll be starting enrollment soon," she told *Primary Care Optometry News*. "We're working closely with the FDA to understand their requirements and set up a study to meet them."

#### **For Your Information:**

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