Symphony Therapeutics

NanoM Wafer™ Biomimetic Lubricating Bandage

A Long-Lasting Lubricating Biomimetic Artificial Tear Film to Treat Dry Eye Symptoms

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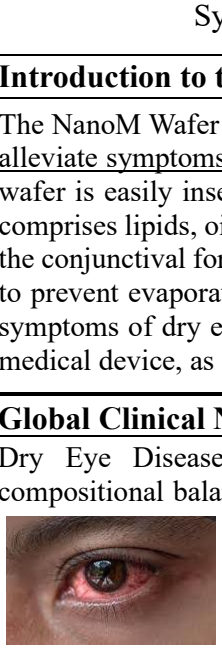
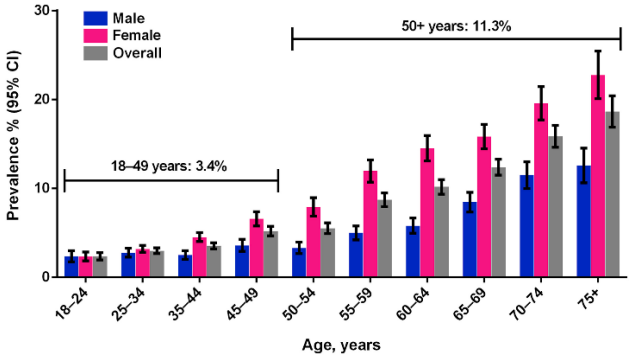
Introduction to the NanoM Wafer Biomimetic Lubricating Bandage

The NanoM Wafer Biomimetic Lubricating Bandage is an ocular insert designed to lubricate the ocular surface, to alleviate symptoms of dry eye. The product has been designed to "mimic" the tear film of the ocular surface. The wafer is easily inserted under the lower eyelid, which slowly dissolves on the eye. Design features of the wafer comprises lipids, oils and a blend of water-soluble film-forming and biocompatible polymers. After placement into the conjunctival fornix (lower eyelid), the wafer "dissolves" into a biphasic oil-water monolayer interface designed to prevent evaporation of water from the ocular surface, creating a "biomimetic lubricating bandage" alleviating symptoms of dry eye disease (DED). From a regulatory perspective, the NanoM Wafer lubricating bandage is a medical device, as it does not contain a drug.

Global Clinical Need

Dry Eye Disease (DED) is caused by loss of compositional balance between the lipid and aqueous portions of tear film, due to molecular dysfunction of the meibomian and lacrimal glands. Additionally, DED can be caused by co-existence of other ocular disorders such as glaucoma, or inflammation caused by allergies, as well as aging, wearing contact lenses, hormonal changes, eye surgery, eye-rubbing, long duration computer use, etc. The disorder is characterized by red eye, itching, excessive tearing, episodes of blurred vision.

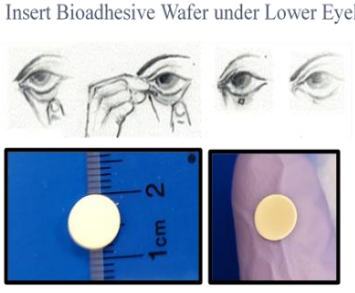




Demographically, DED is prevalent among the elderly and among persons from African and Asian descent. "*Global prevalence of dry eye disease was estimated at 11.59% (standard deviation (SD) = 0.04). For symptomatic disease, the estimate was 9.12% (SD = 0.04), with women 9.5% (SD = 0.05) and men 6.8% (SD = 0.06); prevalence was lowest in North America, 4.6% (SD = 0.03) and highest in Africa, 47.9% (SD = 1.8). For signs, prevalence was 35.2% (SD = 0.3), with woman 34.7% (SD = 0.7) and men 37.6% (SD = 0.7); North America showed the lowest regional prevalence, 3.5%, (SD = 0.4) with Eastern Asia the highest, 42.8% (SD = 0.4). Using TFOS DEWS II diagnostic criteria resulted in a global prevalence of 29.5% (SD = 0.8), with women 28.1% (SD = 1.2) and men 24.9% (SD = 1.4)*".

Treatment modalities have ranged from artificial tear solutions, immunosuppressants, etc. Lacrisert® is a commercial ocular insert, comprised of hydroxypropyl cellulose (HPC) in the form of a cylindrical rod placed in the conjunctival fornix. However, this product has been discontinued due to manufacturing challenges.

How is the NanoM Wafer Biomimetic Lubricating Bandage Used?



- ✓ Dimensions : fits comfortably under lower eyelid
- ✓ Placement: placed in lower conjunctival fornix
- ✓ Turns into a translucent hydrogel upon hydration
- ✓ Fluids permeable (O_2, CO_2, H_2O)
- ✓ >90% H_2O
- ✓ Biodegradable

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The NanoM Wafer lubricating bandage is a sterile, dissolvable, biomimetic ocular insert that is self-administered under the lower eyelid.

NanoM Wafer™ Platform Has Global Patents

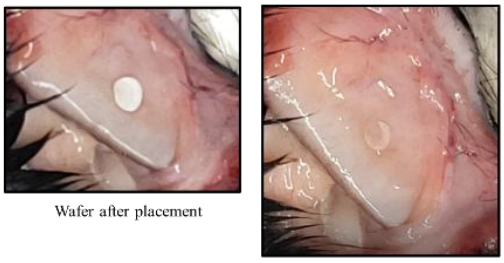
NanoM-Wafer™ is trademark-pending.

The patent portfolio has been fully patented in US, Canada, China, Japan, Singapore, New Zealand, Australia, India, South Africa, Europe.

Patent life to 2035. Additional patent applications on design and use of the NanoM Biomimetic Lubricating Bandage indications have been filed.

NanoM Wafer Attributes

The intricate fenestrations of the NanoM-Wafer offer high contact with mucosal tissue, establishing mucoadhesive bonds



Wafer after placement

Wafer @ 90 s

Dissolution time of wafer can be modulated from 1-3h to 18-24 h

After placement, the NanoM Wafer slowly dissolves on the ocular surface, replenishing both the lipid and aqueous components of the tear film. This alleviates symptoms of dry eye.

In a tolerability study in NZW rabbits, sterilized wafers were administered to the upper conjunctiva of each eye, and the eye assessed for tolerability symptoms: redness, discharge, intraocular pressure increases from baseline, chemosis.

All cohorts were deemed tolerable.

Attribute	Specification
Dissolution Time (h)	Modulable from 1-3h to 18-24h
Size (Diameter, mm)	Diameter 6 mm
Thickness (microns)	150-250
Application Frequency	Once per day
Sterile	Yes
Preservative	None
Packaged	Foil Pack

Potential for Pipeline Utilizing Patented Platform

Intellectual Property • Family of patents over 12 global jurisdictions • Platform technology • IP covers both dissolvable and non-dissolvable wafers • IP covers sustained release of drugs • IP covers wafers with, and without drugs	Dissolvable Wafer: Applications in Ophthalmology • Dry Eye • Allergic Conjunctivitis • Prevention of Inflammation post-cataract surgery • Redness Reduction • Ocular Pain
Removable Wafer for Sustained Release: Applications in Ophthalmology • Sustained delivery for ocular disorders	Wafer Applications (Other Routes) • Urologic • Sinusoidal • Sublingual • Dermal

Regulatory

Due to the absence of drug in the NanoM Wafer Lubricating Bandage, the product will be developed as a medical device.

About Symphony/ Contact Information

Symphony Therapeutics is a wholly-owned subsidiary of Integral BioSystems, a specialty drug delivery company established in 2009.

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