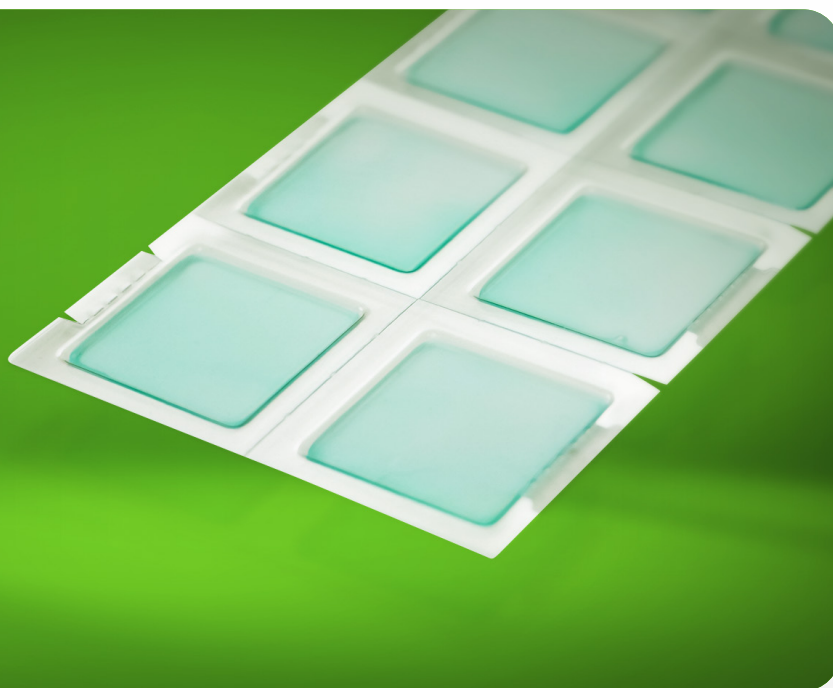




New Dosage Form: NovaFilm™ Oral Transmucosal Films

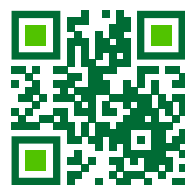
Introducing for the first time to compounding markets around the world, Medisca NovaFilm Oral Transmucosal Films – a new dosage form that will revolutionize your compounding practice. Applied as a thin layer to the oral cavity, Oral Transmucosal Films (OTFs) are an innovative mucoadhesive system that opens numerous possibilities for pharmacists, providers, and patients.



Expanding the Capacity of NovaFilm™ Gel Base

Colliding the power of NovaFilm Gel Base with a cutting-edge molding process, Medisca has expanded the capacity of NovaFilm from versatile mucosal gel to the oral transmucosal film – a two-in-one product for your convenience.

Patent Pending.

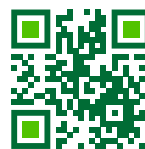


Scan QR Code to LEARN MORE

Product No.: 5498-01

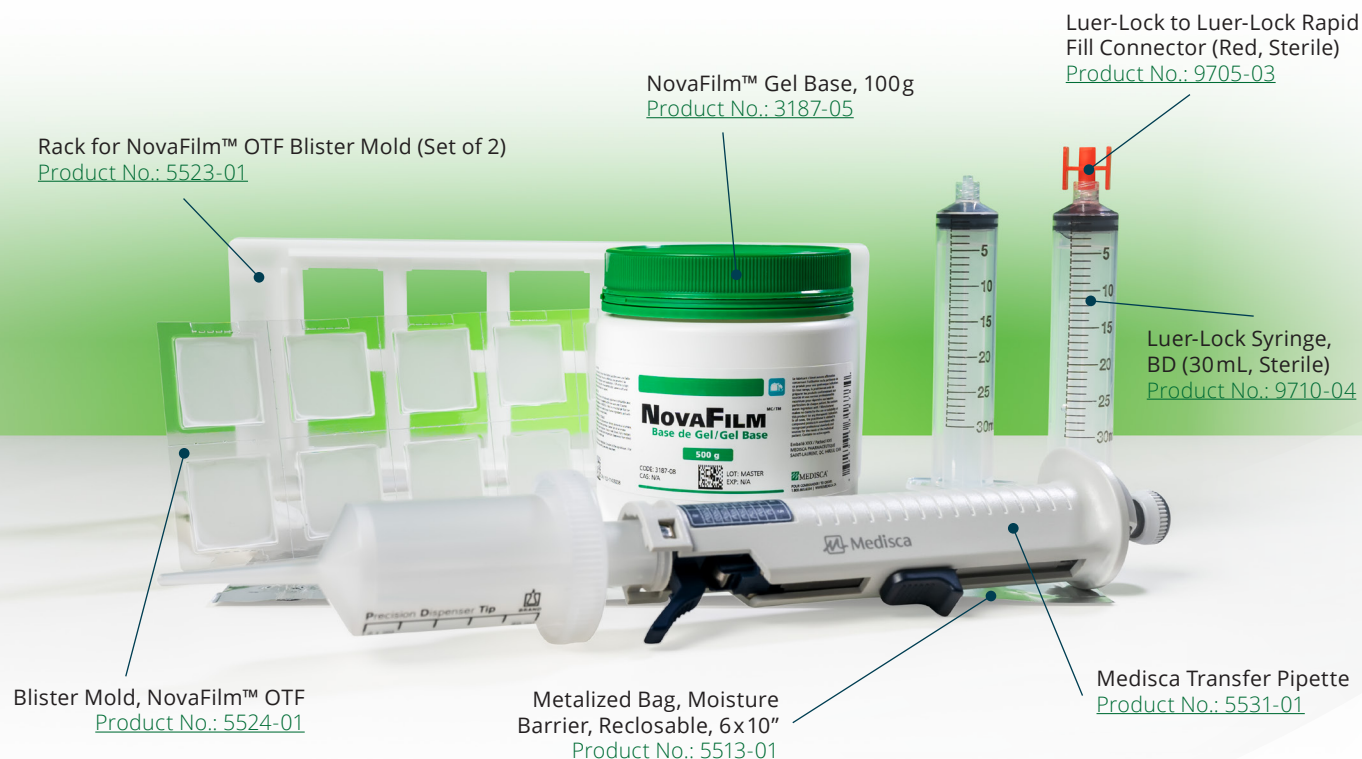
NovaFilm™ Oral Transmucosal Films Kit

Packaged into a Kit Format for Your Convenience



Scan QR Code to
LEARN MORE

Product No.: 5498-01



NovaFilm™ Gel Base, 100g

A concentrated mucoadhesive vehicle that consists of all-natural polymers for delivery of active ingredients to mucosal membranes, including oral, nasal, rectal, and vaginal tissues that can be used, as is, or diluted with purified water or suitable compounding bases. Compatible with a wide range of active ingredients, suitable for both human and veterinary use, and in vitro tested with strong mucoadhesive results.

Medisca Transfer Pipette

Reliable, precise, and durable. The Medisca Transfer Pipette is an easy-to-use device for transferring liquids of various viscosities and densities. Using the accompanying tip, the Medisca Transfer Pipette has a loading capacity of 50 mL and a dispensing volume range of 1 mL to 5 mL. The loading capacity allows for convenient dispenses (up to 48 dispenses) without refill. Included in this purchase are two 50 mL tips, and one adapter.

Blister Mold, NovaFilm™ OTF

Designed for the preparation of OTFs, the NovaFilm OTF Blister Molds are heat resistant (oven safe) and contain 10 cavities with a volume of approximately 1 mL. For added convenience, the Blister Molds also act as the primary packaging system for the films. Once dried, the molds can simply be folded in half, lengthwise, along the middle seam and locked in place with the built-in, perforated tab system. Once locked in, the cavities can be stacked up on top of one another and placed into a Metalized Reclosable Bag, a foil pouch that protects the preparation from moisture.

Rack for NovaFilm™ OTF Blister Mold

Designed to facilitate the preparation of OTFs, this rack is a stackable two-piece reusable system that holds the NovaFilm Blister Molds in place, creating stability and ease of transfer when preparing OTFs. The rack is heat resistant. Not dishwasher safe.

Free Customized Formula

Included in the kit purchase is one free customizable formula using this innovative system.

Preparing Oral Transmucosal Films

As Easy as 1-2-3



Scan QR Code to
VIEW VIDEO
Quick Easy Steps to
Compound OTFs

Ready in three simple steps, the preparation of OTFs using NovaFilm Gel Base is straightforward and non-labor intensive.

Step 1



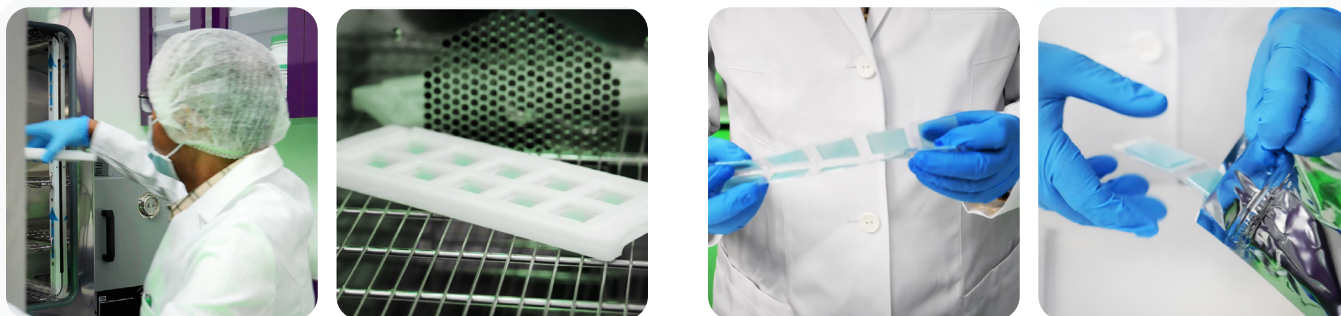
Combine active ingredients into the NovaFilm Gel, which can be streamlined in 3 minutes using the [Medisca MAZ® Mixer](#) or mixed manually using the syringe-to-syringe technique with luer-lock connectors.

Step 2



Fill the Blister Molds using the Medisca Transfer Pipette with a 50mL loading capacity and 1mL metered dispensing capability.

Step 3



Dry the films by baking the preparation in a convection oven, creating a final anhydrous film with a water activity < 0.6 for a default **BUD of 180 days** according to new USP <795> guidelines.

Once cooled, the OTFs can be dispensed, as is, in the blister molds. Simply fold the mold in half along the middle seam, lock in place, and place the preparations in the Metalized Reclosable Bag.

Oral Transmucosal Films

An Out-of-the-Box Solution for Patient Well-Being



Men's Health



Women's Health



Pediatrics



Geriatrics



Veterinary

Leveraging a strong product, innovative thought, and rigorous research and development, Medisca is excited to bring compounders an out-of-the box solution for patient well-being that can revolutionize compounding practices around the globe.



General Sample Formulas

Formula No.	Formula Title
F 009 667	Sildenafil 22mg Oral Transmucosal Films (Solid Suspension, 30 Films)
F 009 670	Progesterone 40mg Oral Transmucosal Films (Solid Suspension, 30 Films)
F 009 673	Naltrexone Hydrochloride 4.5mg Oral Transmucosal Films (Solid Suspension, 30 Films)
F 009 711	Oxytocin 40IU Oral Transmucosal Films (Solid Suspension, 30 Films)

MAZ® Mixer Sample Formulas

Formula No.	Formula Title
F 009 668	Sildenafil 22mg Oral Transmucosal Films (Solid Suspension, 30 Films) (MAZ)
F 009 669	Progesterone 40mg Oral Transmucosal Films (Solid Suspension, 30 Films) (MAZ)
F 009 674	Naltrexone Hydrochloride 4.5mg Oral Transmucosal Films (Solid Suspension, 30 Films) (MAZ)
F 009 712	Oxytocin 40IU Oral Transmucosal Films (Solid Suspension, 30 Films) (MAZ)

“ Adding NovaFilm Oral Transmucosal Films to our product portfolio continues our focus in delivering a convenient and rapid onset dosage form that we know our patients will prefer over traditional forms. Getting to offer a product that embodies our passion for improving male healthcare outcomes is truly a pleasure. We thank Medisca for their ingenuity and perseverance within the compounding world.”

Sam Knight | Director of Pharmacy Operations



NovaFilm OTF Water Activity

According to USP <795> Pharmaceutical Compounding – Non-Sterile Preparations (to be official November 1st 2023), non-aqueous dosage forms may receive a beyond-use date (BUD) limit of 180 days. A non-aqueous dosage form is defined as having a water activity (a_w) less than 0.6. Testing revealed that NovaFilm OTFs have an a_w that is less than 0.6 when dried in the oven or air dried.¹

Process	Description	Water Activity
Oven Dried OTF	Blank NovaFilm OTF preparation placed in forced air convection oven at 50°C for 1 hour	0.342
Air Dried OTF	Blank NovaFilm OTF preparation placed in well ventilated enclosure at room temperature for 16 hours	0.287

The above results are based on water activity testing of compounded blank OTFs using NovaFilm + Purified Water only. Difference in equipment or variation in process or formulation may impact water activity results.

¹ United States Pharmacopeia. (2022). USP <795> Pharmaceutical Compounding – Non-Sterile Preparations. To be official November 1, 2023

For More Information

USA 1-800-932-1039 medisca.com

