

TADALAFILMS® OTF (oral transmucosal film) 4.5mg/8.5mg/12.5mg

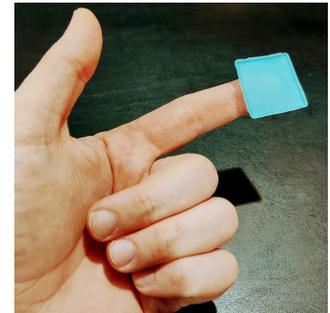
What is tadalafil?

Tadalafil belongs to a class of medications known as PDE-5 inhibitors. Tadalafil is FDA approved to treat erectile dysfunction and benign prostatic hyperplasia. It works to treat erectile dysfunction by increasing blood flow to the penis during sexual stimulation. This increased blood flow can cause an erection. A recent research study suggests that PDE-5 inhibitors may decrease the risk of cardiovascular disease in treated individuals.

What are TADALAFILMS OTF? How do I use them? Why is buccal delivery better?

TADALAFILMS OTF are a unique drug delivery system that allows tadalafil to be absorbed through mucous membranes. This system is an innovative mucoadhesive system which allows for quick absorption and faster onset of action than traditional tablet formulations. It also allows the prescriber to order lower doses, which may produce fewer adverse effects than other tadalafil dosage forms.

This proprietary system is easy to use. The patient simply places the film on the inside of their cheek and the film will do the rest. The film will slowly dissolve over a few minutes.



How are TADALAFILMS OTF supplied?

TADALAFILMS OTF are supplied in plastic sleeves as 4.5mg, 8.5mg, or 12.5mg oral transmucosal films. The films are dispensed in a metalized, moisture barrier bag. They can be made in any strength the prescriber would like.



References:

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2. Tadalafil (Monograph). United States Pharmacopeia XLIII / National Formulary 38. Rockville, MD. US Pharmacopeial Convention, Inc. 2020: 4203.
3. Tadalafil Systemic. Thomson Micromedex. USP DI – Drug Information for the Health Care Professional, 26th Edition. Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 2753.
4. Robert A Kloner, MD, PhD, Eric Stanek, Pharm D, Christopher L Crowe, MPH, Mukul Singhal, PhD, Rebecca S Pepe, MPH, Julia Bradsher, PhD, MBA, Raymond C Rosen, PhD, Effect of phosphodiesterase type 5 inhibitors on major adverse cardiovascular events and overall mortality in a large nationwide cohort of men with erectile dysfunction and cardiovascular risk factors: A retrospective, observational study based on healthcare claims and national death index data, *The Journal of Sexual Medicine*, Volume 20, Issue 1, January 2023, Pages 38–48, <https://doi.org/10.1093/jsxmed/qdac005>
5. USP <795>. United States Pharmacopeia XLIII / National Formulary 38. Rockville, MD. US Pharmacopeial Convention, Inc. 2020: 7025.