ESOKALLI TESTOSTERONE BOOSTER ORAL DISSOLVING FILM- esokalli testosterone booster oral dissolving film film, soluble Guangzhou Yixin Cross-border E-commerce Co., Ltd.

Active ingredients (in each film)

Tadalafil 40 mg - Erectile dysfunction treatment Vardenafil 20 mg - Erectile dysfunction treatment

Purpose

Phosphodiesterase type 5 (PDE5) inhibitors

Uses

For the treatment of erectile dysfunction (ED)

Warnings

For adult men only.

Do not use if you:

take nitrate medicines (such as nitroglycerin)
have severe heart disease or very low blood pressure
are allergic to tadalafil, vardenafil, or any ingredient in this product
have galactose intolerance, total lactase deficiency, or glucose-galactose malabsorption

Dosage and Administration

- Take 1 oral film as a single dose.
- Administer orally by placing on the tongue until dissolved.
- Administer approximately 0.5 to 4 hours prior to anticipated sexual activity.
- Do not exceed 1 dose in 24 hours.

When using this product you may experience:

headache, flushing, indigestion, nasal congestion, dizziness, muscle pain, back pain, nausea, rash, or visual disturbances

Stop use and ask a doctor if:

you experience chest pain, fainting, sudden vision or hearing loss an erection lasts longer than 4 hours (priapism). This is a medical emergency.

Contraindications

Not for use in pregnant or breastfeeding women Not for use in children under 18 years

Inactive ingredients

Film-forming polymers, stabilizers, sweeteners, flavoring agents.

PRINCIPAL DISPLAY PANEL









ESOKALLI TESTOSTERONE BOOSTER ORAL DISSOLVING FILM

esokalli testosterone booster oral dissolving film film, soluble

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84778-085	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TADALAFIL (UNII: 742SXX0ICT) (TADALAFIL - UNII:742SXX0ICT)	TADALAFIL	40 mg in 100 mg	
VARDENAFIL (UNII: UCE6F4125H) (VARDENAFIL - UNII:UCE6F4125H)	VARDENAFIL	20 mg in 100 mg	

Inactive Ingredients			
Ingredient Name	Strength		
HYPROMELLOSES (UNII: 3NXW29V3WO)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
SUCROSE (UNII: C151H8M554)			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84778-085- 01	1 in 1 BOX	08/24/2025	
1		60 mg in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:84778-085- 02	2 in 1 BOX	08/24/2025	
2		60 mg in 1 PATCH; Type 0: Not a Combination Product		
3	NDC:84778-085- 03	4 in 1 BOX	08/24/2025	
3		60 mg in 1 PATCH; Type 0: Not a Combination Product		
4	NDC:84778-085- 04	8 in 1 BOX	08/24/2025	
4		60 mg in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	08/24/2025	

Labeler - Guangzhou Yixin Cross-border E-commerce Co., Ltd. (455800881)

Establishment				
Name	Address	ID/FEI	Business Operations	
Guangzhou Yixin Cross-border E-commerce Co., Ltd.		455800881	manufacture(84778-085) , label(84778- 085)	

Revised: 9/2025 Guangzhou Yixin Cross-border E-commerce Co., Ltd.