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# The Medical Letter®

## on Drugs and Therapeutics

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### IN BRIEF

## Vybrique – Sildenafil Oral Film for Erectile Dysfunction

The FDA has approved *Vybrique* (IBSA), an oral film formulation of the phosphodiesterase type 5 (PDE5) inhibitor sildenafil, for treatment of erectile dysfunction (ED). Sildenafil oral tablets (*Viagra*, and generics) have been available since 1998. The manufacturer is promoting the new product as a “discreet, on-the-go” option that can be taken without water.

#### Pronunciation Key

*Vybrique*: vye breek'

**STANDARD TREATMENT** – Oral PDE5 inhibitors (see Table 1) are generally used for initial treatment of ED. A nonmedicated, alcohol-based topical gel (*Eroxon*) is authorized by the FDA for sale over the counter for treatment of erectile dysfunction in men  $\geq 22$  years old.<sup>1</sup> Other treatment options include vacuum-assisted erection devices, intraurethral or intracavernosal alprostadil, and penile implants.<sup>2</sup> Low-intensity extracorporeal shockwave therapy (not approved by the FDA) has gained popularity for treatment of ED, but quality evidence demonstrating its long-term effectiveness is lacking.<sup>3</sup>

**MECHANISM OF ACTION** – Sildenafil is a selective inhibitor of PDE5. Inhibition of PDE5 increases cyclic guanosine monophosphate (cGMP) levels in the corpus cavernosum, which leads to smooth muscle relaxation and inflow of blood.

**CLINICAL STUDIES** – FDA approval of sildenafil oral film was based on earlier trials with sildenafil tablets and one placebo-controlled trial (summarized in the package insert) in 475 men with ED in which the rate of successful sexual intercourse attempts over 12 weeks was significantly higher in men who used sildenafil oral film.

**ADVERSE EFFECTS** – Adverse effects of sildenafil include headache, flushing, dyspepsia, sudden vision loss, nasal congestion, and back pain. Prolonged erection/priapism can occur. Nonarteritic anterior ischemic optic neuropathy (NAION), retinal detachment, sudden hearing loss, decreased blood pressure, cardiovascular or cerebrovascular events, and syncope have been reported with PDE5 inhibitors.

**DRUG INTERACTIONS** – Like the other PDE5 inhibitors, sildenafil is metabolized by CYP3A4. Inhibitors of CYP3A4 can markedly increase sildenafil serum concentrations.<sup>4</sup> All PDE5 inhibitors can increase the hypotensive effects of organic nitrates such as nitroglycerin and guanylate cyclase stimulators such as riociguat; they are contraindicated for

Table 1. Oral PDE5 Inhibitors for Erectile Dysfunction

Drug	Formulations	Usual Dosage <sup>1</sup>	Cost <sup>2</sup>
Avanafil – generic <i>Stendra</i> (Petros)	50, 100, 200 mg tabs	100 mg PRN ~15 min before sexual activity (max 200 mg once/day)	\$56.30 70.00 <sup>3</sup>
Sildenafil – generic <i>Viagra</i> (Viatris) <i>Vybrique</i> (IBSA)	25, 50, 100 mg tabs 25, 50, 75, 100 mg films	50 mg PRN ~1 hr before sexual activity <sup>4</sup> (max 100 mg once/day)	0.30 87.40 10.00
Tadalafil – generic <i>Cialis</i> (Lilly)	2.5, 5, 10, 20 mg tabs	10 mg PRN $\geq 30$ min before sexual activity (max 20 mg once/day) or 2.5-5 mg once/day <sup>5</sup>	0.30 56.30
Vardenafil – generic	2.5, 5, 10, 20 mg tabs; 10 mg ODT	10 mg PRN ~1 hr before sexual activity (max 20 mg once/day)	4.70 29.00

ODT = orally disintegrating tablet

1. Dosage adjustments may be needed for hepatic or renal impairment or for drug interactions.

2. Approximate WAC for one PRN dose. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. April 5, 2026. Reprinted with permission by First Databank, Inc. All rights reserved. ©2026. www.fdbhealth.com/policies/drug-pricing-policy.

3. Cost without insurance at hims.com.

4. Can be taken 30 minutes to 4 hours before sexual activity.

5. Taken at the same time each day without regard to sexual activity.

use in patients taking these drugs. They may also potentiate the antihypertensive effects of alpha blockers, other antihypertensive drugs, and alcohol.

**DOSAGE AND ADMINISTRATION** – *Vybrique* is available for home delivery. It is supplied in cartons containing 4 or 8 individually packaged oral films, each containing 25, 50, 75, or 100 mg of sildenafil. The film should be placed on the tongue and swallowed with saliva once it has dissolved; it should not be cut or chewed. The recommended dosage is 50 mg taken as needed about one hour (30 minutes to 4 hours) before sexual activity; the dose can be increased to a maximum of 100 mg. Only one dose should be taken each day. The recommended starting dosage is 25 mg in patients who are taking a strong CYP3A4 inhibitor or alpha blocker, have hepatic or severe renal impairment, or are >65 years old. ■

1. Eroxon – an OTC gel for erectile dysfunction. *Med Lett Drugs Ther* 2024; 66:181.
2. AL Burnett et al. Erectile dysfunction: AUA guideline. *J Urol* 2018; 200:633.
3. Shockwave therapy for erectile dysfunction. *Med Lett Drugs Ther* 2023; 65:190.
4. Inhibitors and inducers of CYP enzymes, P-glycoprotein, and other transporters. *Med Lett Drugs Ther* 2023 January 25 (epub). Available at: [www.medicalletter.org/downloads/CYP\\_PGP\\_Tables.pdf](http://www.medicalletter.org/downloads/CYP_PGP_Tables.pdf).

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