

Chewtadzy (tadalafil) – New drug approval

- On June 28, 2024, the [FDA approved](#) ANI Pharmaceuticals' [Chewtadzy \(tadalafil\)](#) chewable tablets, for the treatment of erectile dysfunction (ED) in adult males; treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in adult males; and treatment of ED and the signs and symptoms of BPH (ED/BPH) in adult males.
 - If Chewtadzy is used with finasteride to initiate BPH treatment, such use is recommended for up to 26 weeks because the incremental benefit of tadalafil decreases from 4 weeks until 26 weeks, and the incremental benefit of tadalafil beyond 26 weeks is unknown.
 - Chewtadzy is not indicated for once daily use for ED because dosing is not possible in such patients (the recommended dosage for this indication cannot be achieved with the lowest available strength).
- Tadalafil is a phosphodiesterase 5 (PDE5) inhibitor. It is currently available in several formulations, including a [generic tablet](#) for the same indications as Chewtadzy.
- Chewtadzy is contraindicated in patients:
 - Who are using any form of organic nitrate, either regularly and/or intermittently.
 - With a known serious hypersensitivity reaction to tadalafil or any of the components of Chewtadzy
 - Who are using a guanylate cyclase stimulator, such as riociguat.
- Warnings and precautions for Chewtadzy include cardiovascular risk; potential for drug interactions when taking Chewtadzy for once daily use; prolonged erection and priapism; ocular adverse reactions; sudden hearing loss; hypotension with concomitant use of alpha-blockers and antihypertensives; hypotension with concomitant use of alcohol; concomitant use of potent inhibitors of CYP3A4; combination with other PDE5 inhibitors or erectile dysfunction therapies; effects of bleeding; counseling patients about sexually transmitted diseases; and consideration of other urological conditions prior to initiating treatment for BPH.
- The most common adverse reactions ($\geq 2\%$) with Chewtadzy use were headache, dyspepsia, back pain, myalgia, nasal congestion, flushing, and pain in limb.
- The recommended starting dosage for Chewtadzy for use as needed for ED in most patients is 10 mg orally, taken prior to anticipated sexual activity, not more frequently than once daily.
 - If needed, the dosage can be increased to 20 mg or decreased to 5 mg orally, not more frequently than once daily based on individual efficacy and tolerability.
- The recommended dosage for BPH is 5 mg orally once daily.
 - When used concomitantly with finasteride, the recommended Chewtadzy dosage is 5 mg orally once daily for up to 26 weeks.
- The recommended dosage for ED/BPH is 5 mg orally once daily without regard to timing of sexual activity.

- ANI Pharmaceuticals' launch plans for Chewtadzy are pending. Chewtadzy will be available as a 5 mg, 10 mg, and 20 mg chewable tablet.



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