tadliq®

(Tadalafil) Oral Suspension

20 mg/5 mL

The First and Only FDA-approved Liquid Oral Suspension of Tadalafil

For adult patients with pulmonary arterial hypertension who have dysphagia or difficulty swallowing tablets

tadliq.com

DIFFICULTY SWALLOWING & THE NEED FOR AN ORAL LIQUID SUSPENSION

Patients with pulmonary arterial hypertension (PAH) may also suffer from dysphagia, the medical term used to describe difficulty swallowing. Co-morbidities are often a factor in the prevalence of dysphagia. For instance, scleroderma is a co-morbid condition that can affect up to 40% of PAH patients.[1] Scleroderma presents with significant gastrointestinal involvement commonly in the esophagus, leading to dysphagia.

DYSPHAGIC PATIENTS:

2x more likely to die while in the hospital[2]

33% more likely to need nursing home care

3.8 days longer in the hospital on average

$6,243 higher hospital costs on average

Dysphagia can include difficulty starting a swallow (oropharyngeal dysphagia), issues in the throat (pharyngeal dysphagia), and the sensation of food being stuck (esophageal dysphagia). Given these complications it's important to optimize treatment plans for these patients.

Unfortunately, liquids derived from crushed/compounded tablets raise concerns about patient safety and efficacy, and they have come under increasing scrutiny from the FDA.

PATIENTS WHO MAY NEED AN ORAL LIQUID

- Scleroderma
- Stroke
- Parkinson's Disease
- ALS
- Multiple Sclerosis
- Cerebral Palsy

READ THIS BEFORE YOU CRUSH/ COMPOUND ANOTHER TABLET

68% to 268% The range of potency compounded products exhibited in a 2006 FDA survey.[2]

Contamination In 2007, the CDC found compounded drugs have a higher risk of contamination.[2]

Costly Protocols Crushing can require expensive safety protocols that take up valuable staff time.

Short Shelf Life Crushed and compounded products can have variable and very costly, short shelf lives.

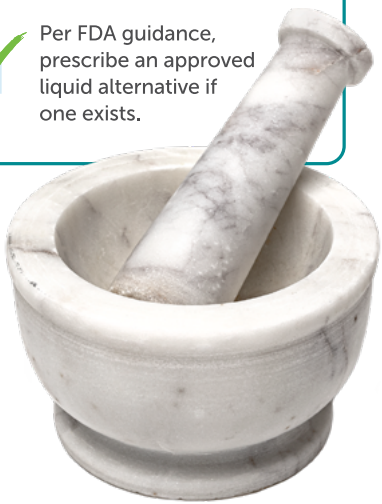
THE RISKS AND CONCERNS OF CRUSHING/COMPOUNDING

Patients who have difficulty swallowing are often given crushed/compounded formulations of the prescriptions. However, crushed/compounded formulations can exhibit a wide variation in potency due to non-uniformity of compounded materials. These dosing inconsistencies of compounded suspensions have long been a persistent challenge for pharmacists and patients.[3] Crushed/compounded formulations are not tested for safety or efficacy.

Due to fatalities related to contamination, the FDA recently released stricter guidance regarding crushing/ compounding and recommended against using crushed/compounded products considered "essentially copies of a commercially available drug product" without permission, especially if an FDA-approved alternative exists.[4]

Before you crush/compound consider the following:

- ✓ Check if the medication is a NIOSH listed product that is high risk and may cause harm.
- ✓ Check USP-800 guidelines for crushing/compounding hazardous products.
- ✓ Per FDA guidance, prescribe an approved liquid alternative if one exists.



WHAT IS TADLIQ?

For adult patients with issues swallowing, Tadliq® is the only FDA-approved oral liquid suspension of tadalafil for patients with pulmonary arterial hypertension (PAH).

- **The only ready-made, once-daily liquid formulation**
- **Eliminates lengthy and complex preparation of powder formulations**
- **Removes risks associated with unapproved compounded/crushed formulations**

DOSING & ADMINISTRATION

Tadliq is an oral suspension: 20 mg/5 mL.

Starting dose: The recommended dose is 40 mg (10 mL) taken once daily with or without food for adult patients. See full prescribing information for full dosing guidance.

Tadliq is bioequivalent to tadalafil.[5]

THE RIGHT MEDICATION FOR THE RIGHT PATIENT

Choosing Tadliq ensures that patients are getting a safe and ready-made FDA-approved oral liquid formulation that does not require any additional preparation by a pharmacist.

	Tadliq (Tadalafil) Oral Suspension	Crushed & Compounded Tadalafil*/Sildenafil Tablets	Sildenafil Powder
FDA-approved oral liquid formulation:	**Yes**	No	Only after powder has been properly reconstituted by a pharmacist.
Ready made:	**Yes**	No	No
Liquid formulation is FDA tested to ensure potency, efficacy & safety:	**Yes**	No	Only after powder has been properly reconstituted by a pharmacist.
Shelf life of liquid formulation:	**24 months**	Unknown	60 days
Minimal Preparation:	**Yes. Shake & dispense**	No	No. Time consuming 10-step process that must be performed by a pharmacist.

***IMPORTANT: Tadalafil tablets should never be broken, split, or crushed.**[6]

150mL bottle | NDC: 46287-045-15

Important Safety Information

Contraindications

TADLIQ is contraindicated in patients who are using any form of organic nitrate, either regularly or intermittently.

PRESCRIBING TADLIQ

Tadliq is available through select specialty pharmacy (SP) providers

How to Prescribe Tadliq:

1. Download a Tadliq prescription request form at **tadliq.com/specialty**
2. Make sure all necessary information has been provided.
3. Complete the entire form and fax it to a specialty pharmacy or submit it via an e-prescribing platform.
4. The chosen specialty pharmacy will contact your patient to collect any incomplete information, review their insurance coverage with estimated co-pays, and schedule their prescription shipment.

*Visit **tadliq.com/specialty** to download the prescription request form*

Commercially insured patients may pay as little as $0* on each prescription with the EasyPay Co-pay Program.

* Terms and Conditions

Void where prohibited by law. CMP Pharma reserves the right to rescind, revoke or amend this program without notice. Offer not valid for patients eligible for benefits under Medicaid (including Medicaid managed care), Medicare, TRICARE, Veterans Affairs, FEHBP, or similar state or federal programs. Offer void where prohibited, taxed, or otherwise restricted. Offer good only in the U.S.A. No generic substitution with this offer.

IMPORTANT SAFETY INFORMATION

Indications and Usage

TADLIQ® is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability. Studies establishing effectiveness included predominately patients with NYHA Functional Class II – III symptoms and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (23%).

Contraindications

- Concomitant organic nitrates
- Concomitant Guanylate Cyclase (GC) Stimulators
- History of known serious hypersensitivity reaction to TADLIQ, ADCIRCA® or CIALIS®

Warnings and Precautions

- **Hypotension:** Carefully consider whether patients with certain underlying cardiovascular disease could be adversely affected by vasodilatory effects of TADLIQ. Not recommended in patients with pulmonary veno-occlusive disease.
- **Effects on the eye:** Sudden loss of vision could be a sign of non-arteritic ischemic optic neuropathy (NAION) and may be permanent.
- **Hearing impairment:** Cases of sudden decrease or loss of hearing have been reported with tadalafil.
- **Concomitant PDE5 inhibitors:** Avoid use with CIALIS, ADCIRCA or other PDE5 inhibitors.
- **Prolonged erection:** Advise patients to seek emergency treatment if an erection lasts >4 hours.

Adverse Reactions

The most common adverse reaction is headache.
To report SUSPECTED ADVERSE REACTIONS, contact CMP Pharma, Inc. at 1-844-321-1443 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Drug Interactions

- Nitrates: Administration of nitrates within 48 hours after the last dose of TADLIQ is contraindicated.
- Alpha-Blockers: PDE5 inhibitors, including TADLIQ, and alpha-adrenergic blocking agents are both vasodilators with blood- pressure-lowering effects.
- Antihypertensives: PDE5 inhibitors, including TADLIQ, are mild systemic vasodilators.
- Alcohol: Both alcohol and tadalafil, a PDE5 inhibitor, act as mild vasodilators.
- CYP3A Inhibitors/Inducers: Ritonavir, Potent Inhibitors of CYP3A, Potent Inducers of CYP3A.

Dosage and Administration

The recommended dose of TADLIQ is 40 mg (10 mL) taken once daily with or without food.

Please see Full Prescribing Information at www.Tadliq.com

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For more information:
Visit tadliq.com

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1. Pulmonary Hypertension in Scleroderma. University of Michigan Health. Accessed September 19, 2022. https://www.uofmhealth.org/conditions-treatments/rheumatology/pulmonary-hypertension-scleroderma **2.** Gudeman, Jennifer, Michael Jozwiakowski, John Chollet, and Michael Randell. "Potential Risks of Pharmacy Compounding." Drugs in R&D 13, no. 1 (2013): 1-8. doi:10.1007/s40268-013-0005-9. **3.** Kindy K, Sun L, Crites A. Compounding pharmacies have been linked to deaths, illnesses for years. Washington Post. February 7, 2013. **4.** Food Drug Administration Center for Drug Evaluation & Research (2016). Guidance for Industry: Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act (FDA, Maryland) 1-8. doi:10.1007/s40268-013-0005-9. **5.** Data on File 0003 Tadliq Clinical Study for Oral Bioequivalence and Food Effect. **6.** How to take ADCIRCA. Accessed August 17, 2022. https://adcirca.com/patient/how-to-take-adcirca.aspx