

YOU HAVE OPTIONS

 **Liqrev**[®]
(Sildenafil) Oral Suspension

10 mg/mL

 **tadliq**[®]
(Tadalafil) Oral Suspension

20 mg/5 mL



**FDA-approved Ready-made
Oral Liquids for Adults
with Pulmonary Arterial
Hypertension (PAH)**


P H A R M A



liqrev.com | 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 hospital²

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





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

Per FDA guidance, prescribe approved liquid alternatives such as Liqrev or Tadiq

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.

THE RIGHT MEDICATION FOR THE RIGHT PATIENT

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



EASY TO SWALLOW

For patients with issues swallowing, Liqrev® & Tadiq® are the only FDA-approved ready-made oral liquid suspensions made for the treatment of pulmonary arterial hypertension (PAH).



-  Eliminates lengthy and complex preparation of powder formulations
-  Removes risks associated with unapproved crushed/compounded formulations
-  The only FDA-approved ready-made liquid formulations

READY-MADE

No Additional
Preparation Needed

Liqrev (sildenafil). LIQREV is indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) in adults to improve exercise ability and delay clinical worsening.

Tadliq (tadalafil). TADLIQ is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability.



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



***IMPORTANT:** Tadalafil tablets should never be broken, split, or crushed.⁷

DOSING & ADMINISTRATION

Liqrev is an oral suspension: 10 mg/mL.

Recommended Dosage in Adults - The recommended dosage of LIQREV is 20 mg orally three times a day. A calibrated measuring device is recommended to measure and deliver the prescribed dose accurately. Shake well for at least 10 seconds before use.

Pediatric use information is approved for Viatrix Specialty LLC's, REVATIO (sildenafil) tablets. However, because of Viatrix Specialty LLC's marketing exclusivity rights, this drug product is not labeled with that information.

Liqrev is bioequivalent to Revatio (sildenafil) tablets.⁵

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 Adcirca (tadalafil) tablets.⁶



ORDER TODAY!



Tadliq Product Information:

NDC: 46287-045-15
150mL bottle

Liqrev Product Information:

NDC: 46287-055-01
122mL bottle

for more information contact
CMP Support Services

call toll-free at
(844) 267-0001

IMPORTANT SAFETY INFORMATION

Contraindications

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

LIQREV is contraindicated in patients with:

- Concomitant use of organic nitrates in any form, either regularly or intermittently, because of the greater risk of hypotension.
- Concomitant use of riociguat, a guanylate cyclase stimulator. PDE-5 inhibitors, including sildenafil, may potentiate the hypotensive effects of riociguat.
- Known hypersensitivity to sildenafil or any component of the oral suspension. Hypersensitivity, including anaphylactic reaction, anaphylactic shock and anaphylactoid reaction, has been reported in association with the use of sildenafil.

Please see additional important safety information on pages 9 & 10



PRESCRIBING LIQREV & TADLIQ

CMP Support Services is here to help

CMP Support Services is here to support both physicians and patients with accessing Liqrev and/or Tadliq by providing the following:

- ✓ Verifying benefits & securing insurance coverage
- ✓ Providing updates to the prescriber during each step of the process
- ✓ Identifying commercially eligible patients that may qualify for co-pay assistance*
- ✓ Submitting the prescription to the specialty pharmacy provider to dispense

How to Prescribe:

Option 1: CMP Support Services

1. Download a prescription form at liqrev.com/form or tadliq.com/form or get a paper copy mailed to you by calling us at **(844) 267-0001**.
2. Fax the completed form to CMP Support Services at **(844) 267-0020**.

Option 2: Direct to Specialty Pharmacy

1. Download a prescription form at liqrev.com/specialty or tadliq.com/specialty.
2. Complete the entire form and fax to a specialty pharmacy or submit via an e-Prescribing platform.

* Terms and conditions apply. Visit tadliq.com/hub for more program information.

Patients pay
as little as

\$0*

on each prescription
using the EasyPay Card



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.

LIQREV IMPORTANT SAFETY INFORMATION

Indications and Usage

Adults

LIQREV is indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) in adults to improve exercise ability and delay clinical worsening.

Pediatric use information is approved for Viatrix Specialty LLC's, REVATIO (sildenafil) tablets. However, because of Viatrix Specialty LLC's marketing exclusivity rights, this drug product is not labeled with that information.

Contraindications

LIQREV is contraindicated in patients with:

- Concomitant use of organic nitrates in any form, either regularly or intermittently, because of the greater risk of hypotension.
- Concomitant use of riociguat, a guanylate cyclase stimulator. PDE-5 inhibitors, including sildenafil, may potentiate the hypotensive effects of riociguat.
- Known hypersensitivity to sildenafil or any component of the oral suspension. Hypersensitivity, including anaphylactic reaction, anaphylactic shock and anaphylactoid reaction, has been reported in association with the use of sildenafil.

Warnings and Precautions

- Vasodilation effects may be more common in patients with hypotension or on antihypertensive therapy.
- Use in pulmonary veno-occlusive disease (PVOD) may cause pulmonary edema and is not recommended.
- Hearing or visual impairment: Seek medical attention if sudden decrease or loss of vision or hearing occurs.
- Pulmonary hypertension (PH) secondary to sickle cell disease: LIQREV may cause serious vaso-occlusive crises.

Adverse Reactions

Adults: Headache, dyspepsia, flushing, pain in limb, myalgia, back pain, and diarrhea

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** - Concomitant use of LIQREV with nitrates in any form is contraindicated
- **Strong CYP3A Inhibitors** - Concomitant use of LIQREV with strong CYP3A inhibitors is not recommended.
- **Moderate-to-Strong CYP3A Inducers** - Concomitant use of LIQREV with moderate-to-strong CYP3A inducers (such as bosentan) decreases the sildenafil exposure.
- **Concomitant PDE-5 inhibitors** - Avoid use with VIAGRA or other PDE-5 inhibitors.

Dosage and Administration

Recommended Dosage in Adults - The recommended dosage of LIQREV is 20 mg orally three times a day. A calibrated measuring device is recommended to measure and deliver the prescribed dose accurately. Shake well for at least 10 seconds before use.

Pediatric use information is approved for Viatrix Specialty LLC's, REVATIO (sildenafil) tablets. However, because of Viatrix Specialty LLC's marketing exclusivity rights, this drug product is not labeled with that information.

TADLIQ 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.



To view full prescribing information please visit
liqrev.com/prescribing-information
tadliq.com/prescribing-information



 **Liqrev**
(Sildenafil) Oral Suspension

10 mg/mL

 **tadliq**[®]
(Tadalafil) Oral Suspension

20 mg/5 mL



**FDA-approved and ready-made for immediate use:
just shake and dispense**



**Eliminates lengthy and complex preparation of
powder formulations**



**Removes risks associated with unapproved
compounded formulations**

**For more information call CMP Support Services
toll-free at (844) 267-0001 | Mon-Friday 8am-5pm ET**

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 Liqrev Clinical Study for Oral Bioequivalence and Food Effect. 6. Data on File 0004 Liqrev Clinical Study for Oral Bioequivalence and Food Effect. 7. How to take ADCIRCA. Accessed August 17, 2022. <https://adcirca.com/patient/how-to-take-adcirca.aspx>

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