YUTREPIA™ (treprostinil) inhalation powder is NOW APPROVED for PAH and PH-ILD patients

NDC Number[1]	NDC Description	Package Size	CuraScript SD Item No.
72964-011-01	YUTREPIA 26.5 mcg	7 day supply / 28 capsules	482455
72964-012-01	YUTREPIA 53 mcg	7 day supply / 28 capsules	488569
72964-013-01	YUTREPIA 79.5 mcg	7 day supply / 28 capsules	488577
72964-014-01	YUTREPIA 106 mcg	7 day supply / 28 capsules	488585

CuraScript SD is a specialty distributor for YUTREPIA and can be reached via the contact information below to provide your institution with a price quote for drug and supplies, or to support processing your order.

Contact CuraScript SD to sign up for an account and/or to obtain your YUTREPIA price quote:

CuraScript SD Rare Disease Customer Service
Phone: 877.900.9223 • Fax: 866.628.8942
Email: **wholesalefax@curascript.com**

INDICATION

- YUTREPIA is a prostacyclin mimetic indicated for the treatment of:
  - Pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability. Studies establishing effectiveness predominately included patients with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated with connective tissue diseases (33%).
  - Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. The study establishing effectiveness predominately included patients with etiologies of idiopathic interstitial pneumonia (IIP) (45%) inclusive of idiopathic pulmonary fibrosis (IPF), combined pulmonary fibrosis and emphysema (CPFE) (25%), and WHO Group 3 connective tissue disease (22%).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- None

WARNINGS AND PRECAUTIONS

- Treprostinil is a pulmonary and systemic vasodilator. In patients with low systemic arterial pressure, treatment with treprostinil may produce symptomatic hypotension.
- Treprostinil inhibits platelet aggregation and increases the risk of bleeding.
- Co-administration of a cytochrome P450 (CYP) 2C8 enzyme inhibitor (e.g., gemfibrozil) may increase exposure (both C_{max} and AUC) to treprostinil. Co-administration of a CYP2C8 enzyme inducer (e.g., rifampin) may decrease exposure to treprostinil. Increased exposure is likely to increase adverse events associated with treprostinil administration, whereas decreased exposure is likely to reduce clinical effectiveness.

IMPORTANT SAFETY INFORMATION, cont'd

WARNINGS AND PRECAUTIONS, cont'd

- Like other inhaled prostaglandins, YUTREPIA may cause acute bronchospasm. Patients with asthma or chronic obstructive pulmonary disease (COPD), or other bronchial hyperreactivity, are at increased risk for bronchospasm.
- Ensure that such patients are treated optimally for reactive airway disease prior to and during treatment with YUTREPIA.

DRUG INTERACTIONS/SPECIFIC POPULATIONS

- The concomitant use of treprostinil with diuretics, antihypertensives, or other vasodilators may increase the risk of symptomatic hypotension.
- Human pharmacokinetic studies with an oral formulation of treprostinil (treprostinil diolamine) indicated that co-administration of the cytochrome P450 (CYP) 2C8 enzyme inhibitor, gemfibrozil, increases exposure (both C_{max} and AUC) to treprostinil. Co-administration of the CYP2C8 enzyme inducer, rifampin, decreases exposure to treprostinil. It is unclear if the safety and efficacy of treprostinil by the inhalation route are altered by inhibitors or inducers of CYP2C8.
- Limited case reports of treprostinil use in pregnant women are insufficient to inform a drug-associated risk of adverse developmental outcomes. However, pulmonary arterial hypertension is associated with an increased risk of maternal and fetal mortality. There are no data on the presence of treprostinil in human milk, the effects on the breastfed infant, or the effects on milk production.
- Safety and effectiveness in pediatric patients have not been established.
- Placebo-controlled clinical studies of treprostinil inhalation solution did not include sufficient numbers of patients aged 65 years and over to determine whether they respond differently from younger patients. The open-label INSPIRE study in patients with PAH included 28 patients aged 65 and over in which no age-related differences were noted. In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of hepatic, renal, or cardiac dysfunction, and of concomitant diseases or other drug therapy.
- Uptitrate slowly when treating patients with hepatic insufficiency because of the risk of an increase in systemic exposure which may lead to an increase in dose-dependent adverse effects. Treprostinil has not been studied in patients with severe hepatic insufficiency.
- No dose adjustments are required in patients with renal impairment. Treprostinil is not cleared by dialysis.

ADVERSE REACTIONS

- The safety and tolerability of YUTREPIA was evaluated in an open label study (INSPIRE) of 121 patients with PAH (WHO Group 1 and NYHA Functional Class II [80 patients] and Class III [41 patients]) followed for up to 2 months. The most commonly reported adverse reactions included cough, headache, throat irritation, dizziness, which are known side effects of treprostinil inhalation solution. The adverse reactions in the INSPIRE study were consistent with those observed in previous studies of inhaled treprostinil.

For additional safety information please see accompanying full Prescribing Information or visit yutrepia.com.

You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit http://www.fda.gov/medwatch, or call 1-800-FDA-1088 or contact Liquidia Technologies Inc. at 1-888-393-5732.

Reference: 1. YUTREPIA. Prescribing information. Liquidia Technologies, Inc; 2025

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