YUTREPIA- treprostinil capsule
Liquidia Technologies, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use YUTREPIA™ safely and effectively. See full prescribing information for YUTREPIA™.

YUTREPIA™ (treprostinil) inhalation powder, for oral inhalation
Initial U.S. Approval: 2002

INDICATIONS AND USAGE

- 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%). (1.1)
- 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%). (1.2)

DOSAGE AND ADMINISTRATION

- For oral inhalation only. Do not swallow YUTREPIA capsules. Use only with the provided inhaler (2)
- YUTREPIA should be administered 3 to 5 times per day. The contents of each capsule can be inhaled in 2 breaths. (2.1)
- See *Dosage and Administration* for full instructions on dosing of patients who are treprostinil-naïve or transitioning from treprostinil inhalation solution to YUTREPIA (2.1)

DOSAGE FORMS AND STRENGTHS

YUTREPIA inhalation powder contained in capsule is available in 4 strengths: 26.5 mcg, 53 mcg, 79.5 mcg, 106 mcg (3)

CONTRAINDICATIONS

None (4)

WARNINGS AND PRECAUTIONS

- Treprostinil may cause symptomatic hypotension. (5.1)
- Treprostinil inhibits platelet aggregation and increases the risk of bleeding. (5.2)
- Dosage adjustments may be necessary if inhibitors or inducers of CYP2C8 are added or withdrawn. (5.3, 7.1)
- May cause bronchospasm: Patients with a history of hyperreactive airway disease may be more sensitive. (5.4)

ADVERSE REACTIONS

Most common adverse reactions with YUTREPIA (³10%) are cough, headache, throat irritation, and dizziness. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Liquidia Technologies, Inc. at 1-888-393-LQDA (5732) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
See 17 for PATIENT COUNSELING INFORMATION.

Revised: 6/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Pulmonary Arterial Hypertension

YUTREPIA is 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%).

The effects diminish over the minimum recommended dosing interval of 4 hours; treatment timing can be adjusted for planned activities.

While there are long-term data on use of treprostinil by other routes of administration, nearly all controlled clinical experience with inhaled treprostinil has been on a background of bosentan (an endothelin receptor antagonist) or sildenafil (a phosphodiesterase type 5 inhibitor). The controlled clinical experience was limited to 12 weeks in duration *[see Clinical Studies (14)]*.

1.2 Pulmonary Hypertension Associated with ILD

YUTREPIA is indicated for the treatment of 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%) *[see Clinical Studies (14.2)]*.

2 DOSAGE AND ADMINISTRATION

2.1 Usual Dosage In Adults

YUTREPIA capsules are for oral inhalation only and should be used only with the supplied inhaler. Do not swallow YUTREPIA capsules.

YUTREPIA Dosing in treprostinil-naïve patients:

In patients naïve to treprostinil, therapy should begin with 26.5 mcg 3 to 5 times per day, in 2 breaths based on patient response.

Dosing in patients transitioning from treprostinil inhalation solution (Tyvaso):

Patients transitioning from treprostinil inhalation solution (Tyvaso), can begin YUTREPIA therapy 3 to 5 times per day, in 2 breaths, using the doses specified below (Table 1):

Table 1: YUTREPIA Dosing in Patients Transitioning from Treprostinil Inhalation Solution

Current Tyvaso Dose* (Number of Breaths)	**YUTREPIA Dose mcg**
5 or less breaths	26.5 mcg
6 to 8 breaths	53 mcg
9 to 11 breaths	79.5 mcg

12 to 14 breaths	106 mcg
15 to 17 breaths	132.5 mcg
18 or more breaths	159 mcg

*Each breath of Tyvaso delivers approximately 6 mcg of treprostinil.

In treprostinil-naïve patients and those transitioning from treprostinil inhalation solution, dose increases of 26.5 mcg per dose each week may be implemented, as tolerated. The target maintenance dosage is 79.5 mcg to 106 mcg, 4 times daily.

Doses above 848 mcg per day have not been studied in patients with PAH.

If a scheduled dose is missed, resume therapy as soon as possible at the usual dose.

3 DOSAGE FORMS AND STRENGTHS

YUTREPIA inhalation powder contained in capsule available in 4 strengths:

- 26.5 mcg: opaque yellow cap and clear body capsule with “LIQUIDIA 26.5” in black radial imprint on capsule cap.
- 53 mcg: opaque green cap and clear body capsule with “LIQUIDIA 53” in white radial imprint on capsule cap.
- 79.5 mcg: opaque blue cap and clear body capsule with “LIQUIDIA 79.5” in white radial imprint on capsule cap.
- 106 mcg: opaque purple cap and clear body capsule with “LIQUIDIA 106” in white radial imprint on capsule cap.

4 CONTRAINDICATIONS

None

5 WARNINGS AND PRECAUTIONS

5.1 Risk of Symptomatic Hypotension

Treprostinil is a pulmonary and systemic vasodilator. In patients with low systemic arterial pressure, treatment with treprostinil may produce symptomatic hypotension.

5.2 Risk of Bleeding

Treprostinil inhibits platelet aggregation and increases the risk of bleeding.

5.3 Effect of Other Drugs on Treprostinil

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 *[see*

Drug Interactions (7.1) and Clinical Pharmacology (12.3)].

5.4 Bronchospasm

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.

6 ADVERSE REACTIONS

The following potential adverse reactions are described in Warnings and Precautions (5):

- Decrease in systemic blood pressure *[see Warnings and Precautions (5.1)]*.
- Bleeding *[see Warnings and Precautions (5.2)]*.

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

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. Table 2 lists the adverse reactions that occurred at a rate of at least 4% of the overall INSPIRE safety population. The adverse reactions in the INSPIRE study were consistent with those observed in previous studies of inhaled treprostinil.

Table 2: Adverse Reactions Occurring in ≥ 4% of Patients in the INSPIRE Study

Adverse Reaction	Transition* N=55 n (%)	Add-On† N=66 n (%)
Cough	15 (27)	36 (55)
Headache	14 (25)	18 (27)
Throat Irritation	5 (9)	14 (21)
Dizziness	6 (11)	7 (11)
Diarrhea	3 (6)	8 (12)
Chest Discomfort	5 (9)	5 (8)
Nausea	4 (7)	5 (8)
Dyspnea	3 (6)	3 (5)

Flushing	1 (2)	5 (8)
Oropharyngeal Pain	1 (2)	4 (6)

*Transition: Patients were on stable doses of treprostinil inhalation solution for at least 3 months prior to enrollment in the study and transitioned to treatment with YUTREPIA.
†Add-on: Patients were prostacyclin-naïve and were taking no more than 2 approved oral PAH therapies for at least 3 months at time of enrollment and addition of treatment with YUTREPIA.

6.2 Adverse Reactions Identified in Post-Marketing Experience

The following adverse reaction has been identified during the post-approval use of treprostinil inhalation solution. Because this reaction is reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate the frequency or establish a causal relationship to drug exposure:

- Angioedema

7 DRUG INTERACTIONS

7.1 Effect of Cytochrome P450 Inhibitors and Inducers

In vitro studies of human hepatic microsomes showed that treprostinil does not inhibit cytochrome P450 (CYP) isoenzymes CYP1A2, CYP2A6, CYP2C8, CYP2C9, CYP2C19, CYP2D6, CYP2E1 and CYP3A.

Additionally, treprostinil does not induce cytochrome P450 isoenzymes CYP1A2, CYP2B6, CYP2C9, CYP2C19, and CYP3A.

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 *[see Warnings and Precautions (5.3)]*.

7.2 Effect of Other Drugs on Treprostinil

Drug interaction studies have been carried out with treprostinil (oral or subcutaneous) co-administered with acetaminophen (4 g/day), warfarin (25 mg/day), and fluconazole (200 mg/day), respectively, in healthy volunteers. These studies did not show a clinically significant effect on the pharmacokinetics of treprostinil. Treprostinil does not affect the pharmacokinetics or pharmacodynamics of warfarin. The pharmacokinetics of R- and S-warfarin and the INR in healthy subjects given a single 25 mg dose of warfarin were unaffected by continuous subcutaneous infusion of treprostinil at an infusion rate of 10

ng/kg/min.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Limited case reports of treprostinil use in pregnant women are insufficient to inform a drug-associated risk of adverse developmental outcomes. However, there are risks to the mother and the fetus associated with pulmonary arterial hypertension (see *Clinical Considerations*). In animal studies, no adverse reproductive and developmental effects were seen for treprostinil at $^{3}9$ and $^{3}145$ times the human exposure when based on C_{max} and AUC, respectively, following a single YUTREPIA dose of 79.5 mcg *[see Clinical Pharmacology (12.3)]*.

The estimated background risk of major birth defects and miscarriage for the indicated populations is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Clinical Considerations

Disease-associated maternal and embryo-fetal risk

Pulmonary arterial hypertension is associated with an increased risk of maternal and fetal mortality.

Data

Animal reproduction studies have been conducted with treprostinil via continuous subcutaneous administration and with treprostinil diolamine administered orally. In studies with orally administered treprostinil diolamine, no adverse effect doses for fetal viability/growth, fetal development (teratogenicity), and postnatal development were determined in rats. In pregnant rats, no evidence of harm to the fetus was observed following oral administration of treprostinil diolamine at the highest dose tested (20 mg/kg/day), which represents about 154 and 1479 times the human exposure, when based on C_{max} and AUC, respectively, following a single YUTREPIA dose of 79.5 mcg. In pregnant rabbits, external fetal and soft tissue malformations and fetal skeletal malformation occurred. The dose at which no adverse effects were seen (0.5 mg/kg/day) represents about 9 and 145 times the human exposure, when based on C_{max} and AUC, respectively, following a single YUTREPIA dose of 79.5 mcg. No treprostinil treatment-related effects on labor and delivery were seen in animal studies. Animal reproduction studies are not always predictive of human response.

8.2 Lactation

Risk Summary

There are no data on the presence of treprostinil in human milk, the effects on the breastfed infant, or the effects on milk production.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

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 PAH patients 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.

8.6 Patients with Hepatic Insufficiency

Plasma clearance of treprostinil, delivered subcutaneously, was reduced up to 80% in subjects with mild-to-moderate hepatic insufficiency. 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 *[see Clinical Pharmacology (12.3)]*.

8.7 Patients with Renal Insufficiency

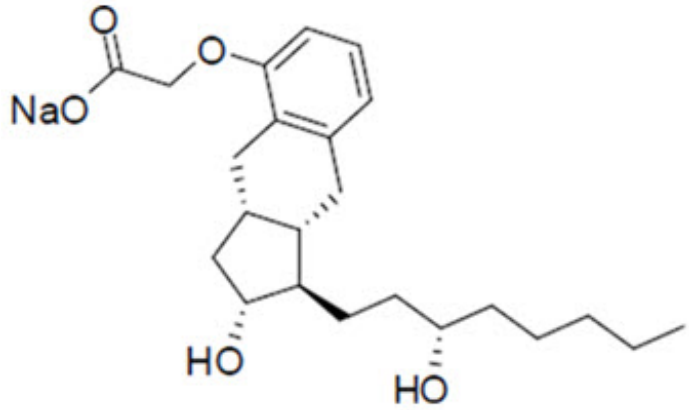
No dose adjustments are required in patients with renal impairment. Treprostinil is not cleared by dialysis *[see Clinical Pharmacology (12.3)]*.

10 OVERDOSAGE

In general, symptoms of overdose with treprostinil include flushing, headache, hypotension, nausea, vomiting, and diarrhea. Provide general supportive care until the symptoms of overdose have resolved.

11 DESCRIPTION

YUTREPIA contains treprostinil sodium, a prostacyclin mimetic. The chemical name for tresprostinil sodium is 2-{[(1R,2R,3aS,9aS)-2-hydroxy-1-[(3S)-3-hydroxyoctyl]-1H,2H,3H,3aH,4H,9H,9aH-cyclopenta[b]naphthalen-5-yl]oxy}acetic acid, sodium salt with the structural formula:



Treprostinil sodium has a molecular formula of $C_{23}H_{33}O_5Na$ and a molecular weight of 412.49 daltons equivalent to 390.5 daltons of Treprostinil.

YUTREPIA inhalation powder contained in a capsule is intended for oral inhalation. The capsule contains white to off-white powder of treprostinil sodium and the inactive ingredients L-leucine, polysorbate 80, sodium chloride, sodium citrate, and trehalose. Each 5 mg of YUTREPIA inhalation powder contains 26.5 mcg of treprostinil, where 26.5 mcg of treprostinil is equivalent to 28 mcg of treprostinil sodium.

The accompanying inhalation device for delivery of YUTREPIA inhalation powder is a disposable plastic device used to inhale the dry powder contained in the HPMC capsule.

The amount of drug delivered to the lungs will vary depending on patient factors such as inspiratory flow and peak inspiratory flow through the inhalation device, which may vary from patient to patient.

Under standardized *in vitro* testing, the inhalation device delivers the following amounts of treprostinil for each of the YUTREPIA inhalation powder capsule strengths:

YUTREPIA Inhalation Powder Delivered Dose

Capsule Strength (treprostinil)	Dose Delivered [a]
26.5 mcg	15.1 mcg
53 mcg	36.0 mcg
79.5 mcg	56.6 mcg
106 mcg	75.7 mcg

[a] Amount of treprostinil delivered from the device mouthpiece under an *in vitro* flow rate of 99 L/min with a collection time of 1.2 seconds (2 L total volume).

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The major pharmacologic actions of treprostinil are direct vasodilation of pulmonary and

systemic arterial vascular beds and inhibition of platelet aggregation.

12.2 Pharmacodynamics

In animals, the vasodilatory effects reduce right and left ventricular afterload and increase cardiac output and stroke volume. Other studies have shown that treprostinil causes a dose-related negative inotropic and lusitropic effect. No major effects on cardiac conduction have been observed. Treprostinil produces vasodilation and tachycardia.

Cardiac Electrophysiology

In a clinical trial of 240 healthy volunteers, single doses of treprostinil inhalation solution 54 mcg (the target maintenance dose per session) and 84 mcg (supratherapeutic inhalation dose) prolonged the corrected QTc interval by approximately 10 ms. The QTc effect dissipated rapidly as the concentration of treprostinil decreased.

12.3 Pharmacokinetics

Absorption

In healthy volunteer studies, the systemic exposure (AUC and C_{max}) post-inhalation was shown to be proportional to the YUTREPIA doses administered (25 mcg – 150 mcg). The treprostinil mean C_{max}, mean AUC_{inf} and median T_{max} following a single inhaled target maintenance dose of 79.5 mcg YUTREPIA were 1.48 ng/mL, 1.04 hr.ng/mL and 0.13 hr, respectively.

Distribution

In vitro treprostinil is 91% bound to human plasma proteins over the 330-10,000 ng/mL concentration range.

Metabolism and Excretion

Of subcutaneously administered treprostinil, only 4% is excreted unchanged in urine. Treprostinil is substantially metabolized by the liver, primarily by CYP2C8. Metabolites are excreted in urine (79%) and feces (13%) over 10 days. Five apparently inactive metabolites were detected in the urine, each accounting for 10-15% of the dose administered. Four of the metabolites are products of oxidation of the 3-hydroxyloctyl side chain and one is a glucuroconjugated derivative (treprostinil glucuronide).

Elimination

Following inhaled administration of YUTREPIA, disposition and elimination is monophasic with a half-life of approximately 30 minutes.

Specific Populations

Hepatic Insufficiency

Plasma clearance of treprostinil, delivered subcutaneously, was reduced up to 80% in subjects presenting with mild-to-moderate hepatic insufficiency. Treprostinil has not been studied in patients with severe hepatic insufficiency *[see Use in Specific Populations (8.6)]*.

Renal Insufficiency

In patients with severe renal impairment requiring dialysis (n=8), administration of a

single 1 mg dose of orally administered treprostinil pre-and post-dialysis resulted in AUC0-inf that was not significantly altered compared to healthy subjects *[see Use in Specific Populations (8.7)]*.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

A two-year rat carcinogenicity study was performed with treprostinil inhalation solution at target treprostinil doses of 5.26, 10.6, and 34.1 mcg/kg/day. There was no evidence for carcinogenic potential associated with treprostinil inhalation in rats at systemic exposure levels up to 35 times following a single YUTREPIA dose of 79.5 mcg *[see Clinical Pharmacology (12.3)]*. *In vitro* and *in vivo* genetic toxicology studies did not demonstrate any mutagenic or clastogenic effects of treprostinil. Treprostinil sodium did not affect fertility or mating performance of male or female rats given continuous subcutaneous (sc) infusions at rates of up to 450 ng treprostinil/kg/min. In this study, males were dosed from 10 weeks prior to mating and through the 2-week mating period. Females were dosed from 2 weeks prior to mating until gestational day 6.

Oral administration of treprostinil diolamine to Tg.rasH2 mice at 0, 5, 10 and 20 mg/kg/day in males and 0, 3, 7.5 and 15 mg/kg/day in females daily for 26 weeks did not significantly increase the incidence of tumors.

Treprostinil diolamine was tested *in vivo* in a rat micronucleus assay and did not induce an increased incidence of micronucleated polychromatic erythrocytes.

13.2 Animal Toxicology and/or Pharmacology

In a 2-year rat study with treprostinil inhalation at target doses of 5.26, 10.6, and 34.1 mcg/kg/day, there were more deaths (11) in the mid- and high-dose treprostinil groups during the first 9 weeks of the study, compared to 1 in control groups. At the high-dose level, males showed a higher incidence of inflammation in teeth and preputial gland, and females showed high incidences of inflammation and urothelial hyperplasia in the urinary bladder. The exposures in rats at mid- and high-dose levels were about 15 and 35 times, respectively, the clinical exposure following a single YUTREPIA dose of 79.5 mcg *[see Clinical Pharmacology (12.3)]*.

14 CLINICAL STUDIES

14.1 Pulmonary Arterial Hypertension (WHO Group 1)

TRIUMPH I was a 12-week, randomized, double-blind, placebo-controlled multi-center study of patients with PAH. The study population included 235 clinically stable patients with pulmonary arterial hypertension (WHO Group 1), nearly all with NYHA Class III (98%) symptoms who were receiving either bosentan (an endothelin receptor antagonist) or sildenafil (a phosphodiesterase-5 inhibitor) for at least three months prior to study initiation. Concomitant therapy also could have included anticoagulants, other vasodilators (e.g., calcium channel blockers), diuretics, oxygen, and digitalis, but not a prostacyclin. These patients were administered either placebo or treprostinil inhalation

solution in four daily treatment sessions with a target dose of 9 breaths (equivalent to 79.5 mcg YUTREPIA) per session over the course of the 12-week study. Patients were predominantly female (82%), had the origin of PAH as idiopathic/heritable (56%), secondary to connective tissue diseases (33%) or secondary to HIV or previous use of anorexigens (12%); bosentan was the concomitant oral medication in 70% of those enrolled, sildenafil in 30%.

The primary efficacy endpoint of the trial was the change in six-minute walk distance (6MWD) relative to baseline at 12 weeks. 6MWD was measured at peak exposure (between 10 and 60 minutes after dosing), and 3-5 hours after bosentan or 0.5-2 hours after sildenafil. Patients receiving treprostinil inhalation solution had a placebo-corrected median change from baseline in peak 6MWD of 20 meters at Week 12 ($p<0.001$).

The distribution of these 6MWD changes from baseline at Week 12 were plotted across the range of observed values (Figure 1). 6MWD measured at trough exposure (defined as measurement of 6MWD at least 4 hours after dosing) improved by 14 meters. There were no placebo-controlled 6MWD assessments made after 12 weeks.

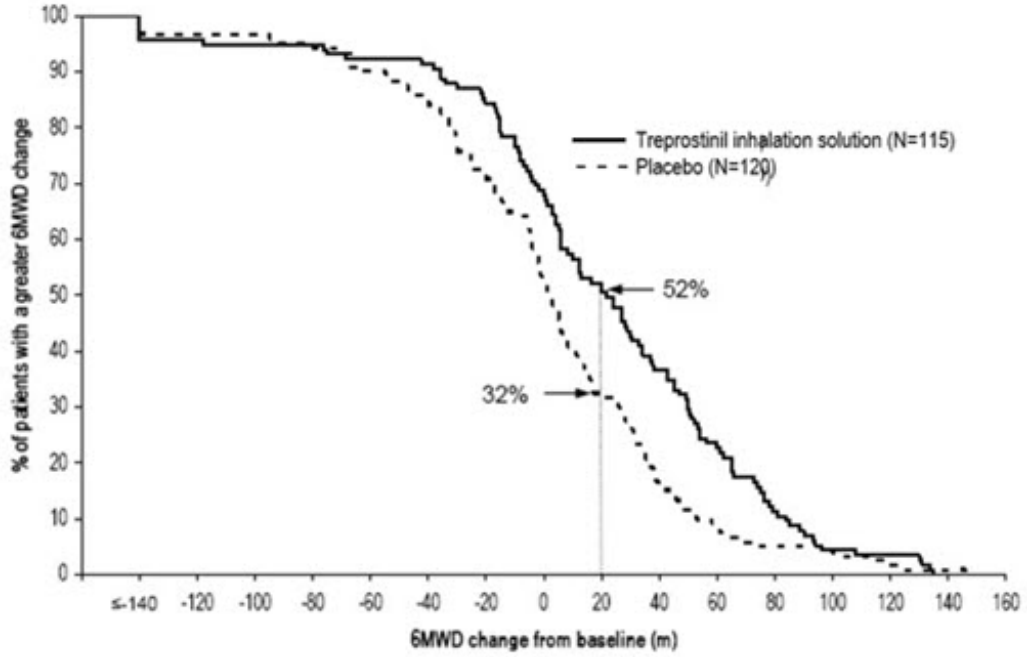


Figure 1. Distributions of 6MWD Changes from Baseline at Week 12 during Peak Plasma Concentration of Treprostinil Inhalation Solution

The placebo-corrected median treatment effect on 6MWD was estimated (using the Hodges-Lehmann estimator) within various subpopulations defined by age quartile, gender, geographic region of the study site, disease etiology, baseline 6MWD quartile, and type of background therapy (Figure 2).

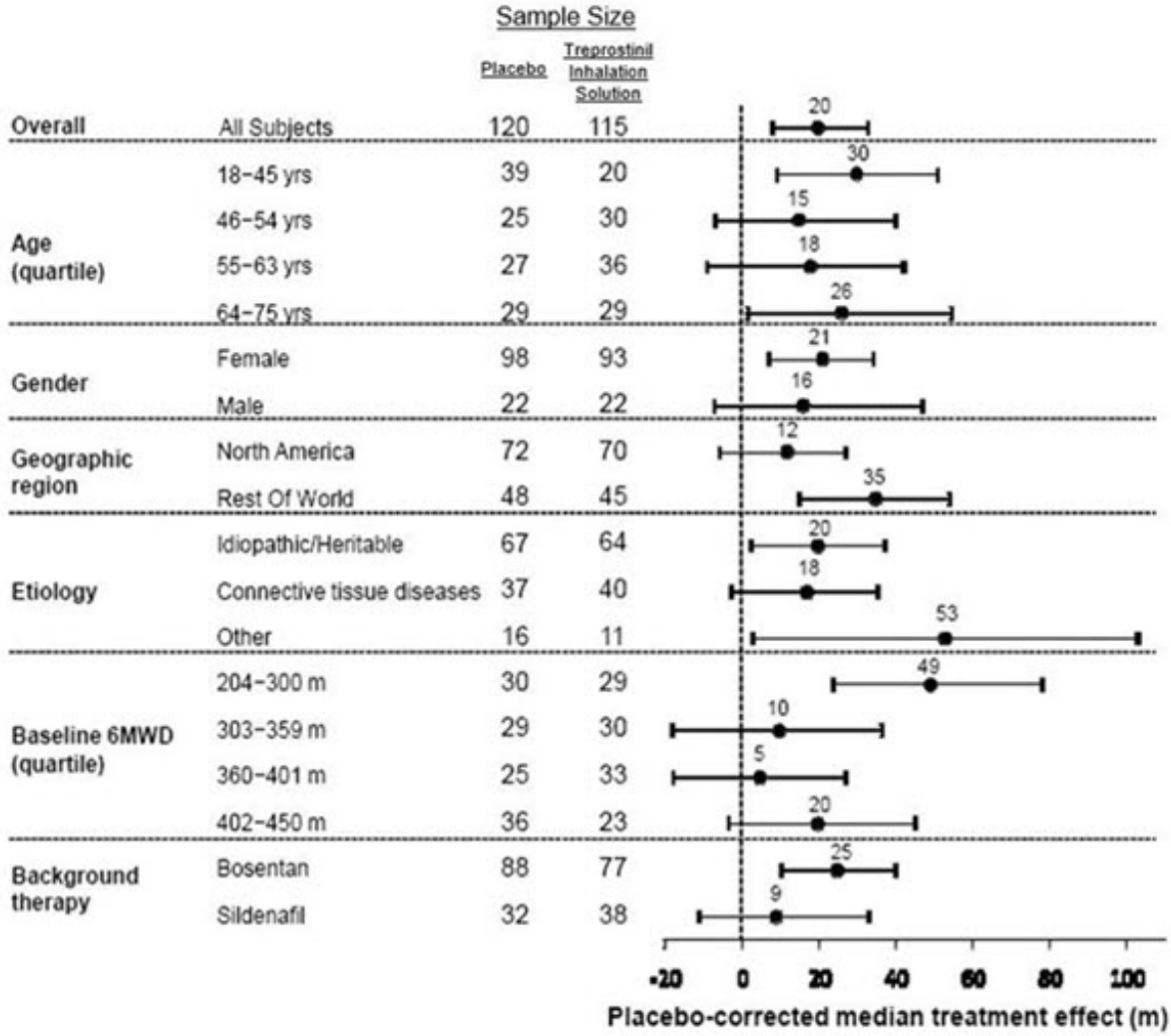


Figure 2. Placebo-Corrected Median Treatment Effect (Hodges-Lehmann estimate with 95% CI) on 6MWD Change from Baseline at Week 12 During Peak Plasma Concentration of Treprostinil Inhalation Solution for Various Subgroups

14.2 Pulmonary Hypertension Associated with ILD (WHO Group 3)

INCREASE was a 16-week, randomized, double-blind, placebo-controlled, multicenter study that enrolled 326 patients with PH-ILD. Enrolled study patients predominately had etiologies of idiopathic interstitial pneumonia (45%) inclusive of idiopathic pulmonary fibrosis, combined pulmonary fibrosis and emphysema (25%), and WHO Group 3 connective tissue disease (22%). The mean baseline 6MWD was 260 meters.

Patients in the INCREASE study were randomized (1:1) to either placebo or treprostinil inhalation solution in four daily treatment sessions with a target dose of 9 breaths (equivalent to 79.5 mcg YUTREPIA) per session and a maximum dose of 12 breaths (equivalent to 106 mcg YUTREPIA) per session over the course of the 16-week study. Approximately 75% of patients randomized to treprostinil inhalation solution titrated up to a dose of 9 breaths, 4 times daily or greater, with 48% of patients randomized to treprostinil inhalation solution reaching a dose of 12 breaths, 4 times daily during the study. The primary efficacy endpoint was the change in 6MWD measured at peak exposure (between 10 and 60 minutes after dosing) from baseline to Week 16. Patients receiving treprostinil inhalation solution had a placebo-corrected median change from baseline in peak 6MWD of 21 meters at Week 16 ($p=0.004$) using Hodges-Lehmann estimate (Figure 3).

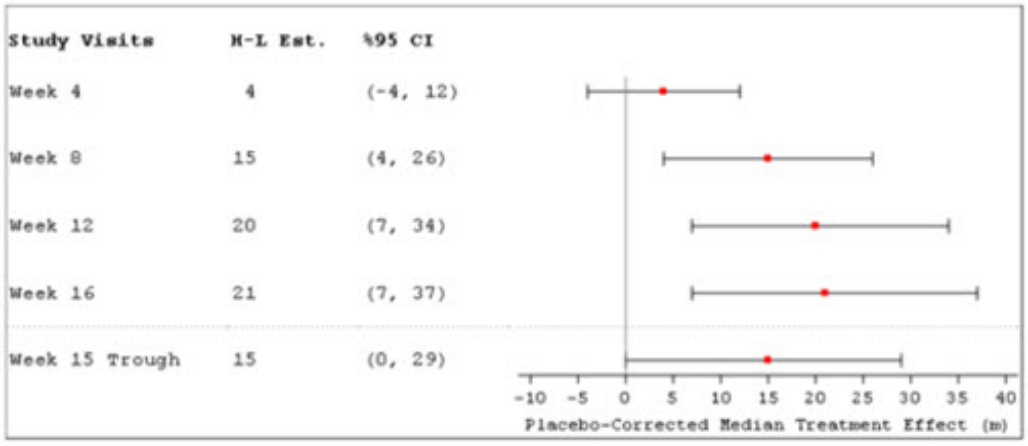


Figure 3: Hodges-Lehmann Estimate of Treatment Effect by Visit for 6MWD at Peak Exposure (PH-ILD)

The treatment effect on 6MWD at Week 16 was consistent for various subgroups, including etiology of PH-ILD, disease severity, age, sex, baseline hemodynamics, and dose (Figure 4).

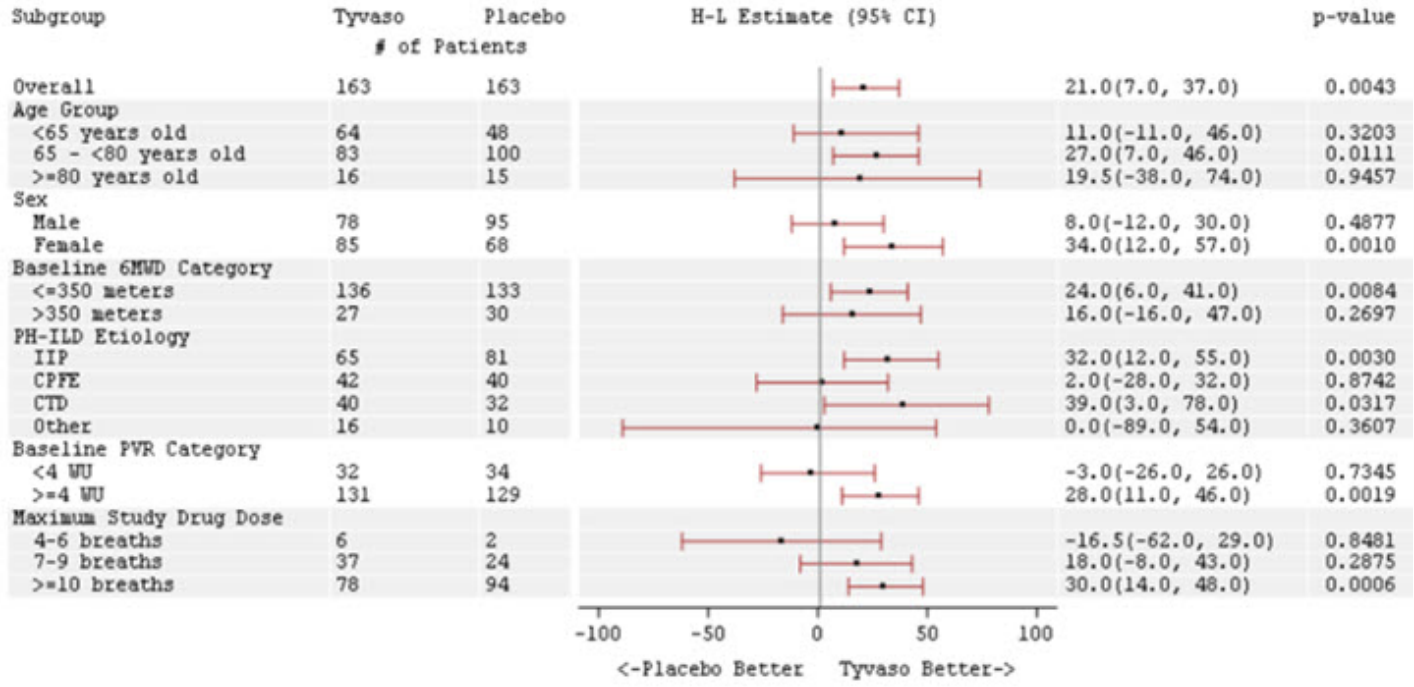


Figure 4: Forest Plot on Subgroup Analyses of Peak 6MWD (Meter) at Week 16 (PH-ILD)

Time to clinical worsening in the INCREASE study was defined as the time of randomization until 1 of the following criteria were met: hospitalization due to a cardiopulmonary indication, decrease in 6MWD >15% from baseline directly related to PH-ILD at 2 consecutive visits and at least 24 hours apart, death (all causes), or lung transplantation. Treatment with treprostinil inhalation solution in patients with PH-ILD resulted in numerically fewer hospitalizations. The numbers of reported deaths were the same for both treatment groups (Table 3). Overall, treatment with treprostinil inhalation solution demonstrated a statistically significant increase in the time to first clinical

worsening event (log-rank test p=0.041; Figure 5), and a 39% overall reduction in the risk of a clinical worsening event (HR=0.61 [95% CI; 0.40, 0.92]; Figure 5).

Table 3: Clinical Worsening Events (PH-ILD)

		Tyvaso n=163 n (%)	Placebo n=163 n (%)	HR (95% CI)
Clinical worsening		37 (22.7%)	54 (33.1%)	0.61 (0.40, 0.92)
First contributing event	**Hospitalization due to a cardiopulmonary indication**	18 (11.0%)	24 (14.7%)	
	Decrease in 6MWD > 15% from baseline directly related to PH-ILD	13 (8.0%)	26 (16.0%)	
	Death (all causes)	4 (2.5%)	4 (2.5%)	
	Lung transplantation	2 (1.2%)	0	

		Tyvaso n=163 n (%)	Placebo n=163 n (%)	HR (95% CI)
First of each event	**Hospitalization due to a cardiopulmonary indication**	21 (12.9)	30 (18.4%)	
	Decrease in 6MWD > 15% from baseline directly related to PH-ILD	16 (9.8%)	31 (19.0%)	
	Death (all causes)	8 (4.9%)	10 (6.1%)	
	Lung transplantation	2 (1.2%)	1 (0.6%)	

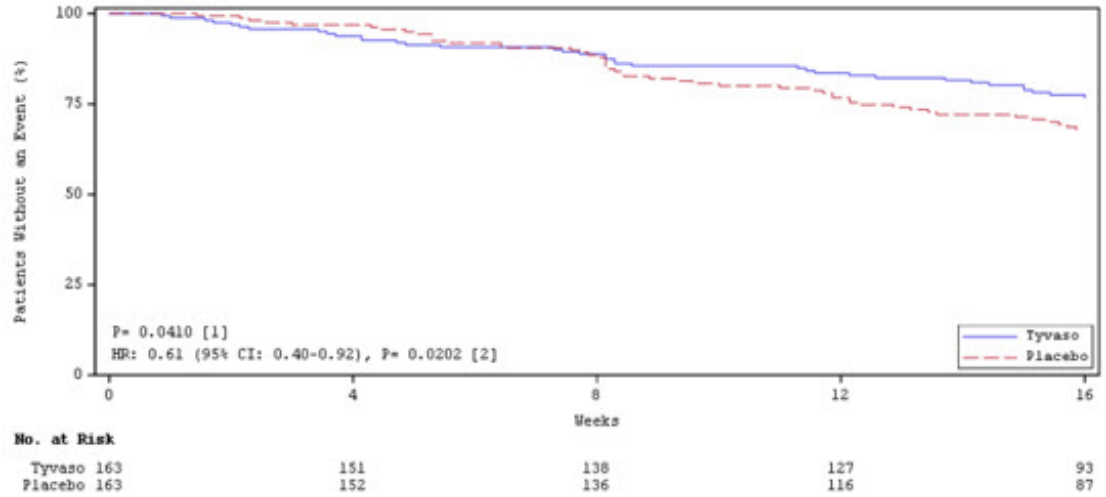


Figure 5: Kaplan-Meier Plot of Time to Clinical Worsening Events (PH-ILD)

16 HOW SUPPLIED/STORAGE AND HANDLING

YUTREPIA is supplied in a carton consisting of 1 capsule based, dry powder inhaler (referred to as “inhaler”), 28 capsules (7 foil blister cards of 4 capsules each), and 7 single-use cleaning brushes. The individual capsule well is connected by an air channel to a separate blister well containing a desiccant strip. Descriptions of YUTREPIA carton by capsule strength are provided in Table 4 below:

Table 4: YUTREPIA Carton Contents by Capsule Strength

Capsule Strength (mcg treprostinil)	Capsule Description	NDC Number
26.5	Opaque yellow cap, clear body, imprinted with “LIQUIDIA 26.5” in black ink radially on cap	72964-011-01
53	Opaque green cap, clear body, imprinted with “LIQUIDIA 53” in white ink radially on cap	72964-012-01
79.5	Opaque blue cap, clear body, imprinted with “LIQUIDIA 79.5” in white ink radially on cap	72964-013-01
106	Opaque purple cap, clear body, imprinted with “LIQUIDIA 106” in white ink radially on cap	72964-014-01

YUTREPIA inhalation powder capsules should only be delivered using the capsule-based inhaler. The off-white plastic inhaler consists of a blue protective cap marked with YUTREPIA and a base with a mouthpiece, capsule chamber, and two blue push buttons. Discard the inhaler device after 7 days of use or 56 actuations, whichever comes first.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

Capsules should remain in the blister to protect them from moisture and light, and each capsule should be removed only when ready to administer a dose.

Keep out of the reach of children.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Instructions for Use).

Train patients in the administration process for YUTREPIA, including dosing, inhaler preparation, administration, cleaning, and maintenance, according to the instructions for use *[see Instructions for Use]*.

To avoid potential interruptions in drug delivery because of equipment malfunction, patients should have access to a back-up.

If a scheduled dose is missed, resume therapy as soon as possible at the usual dose.

Distributed by: Liquidia Technologies, Inc. Morrisville, NC 27560

Instructions for Use

YUTREPIA™ (you-TREP-ee-uh)
(treprostinil)
inhalation powder, for oral inhalation

This Instructions for Use contains information on how to inhale YUTREPIA™. Read these Instructions for Use before you start using YUTREPIA and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

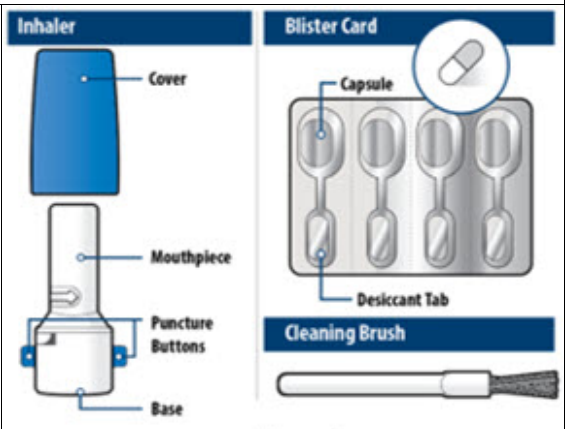
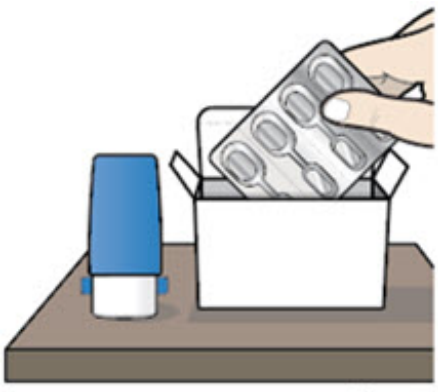
Your healthcare provider should show you or your caregiver how to use YUTREPIA the right way before you use it for the first time.

Important information you need to know before inhaling YUTREPIA inhalation powder:

- **Do not** swallow YUTREPIA capsules. YUTREPIA is for inhalation only.
- Use YUTREPIA as prescribed by your healthcare provider.
- YUTREPIA capsules come in 4 strengths: 26.5 mcg, 53 mcg, 79.5 mcg, and 106 mcg.
- If your prescribed dose is more than 106 mcg, you will need to inhale 2 YUTREPIA capsules. **See Figure C**: Dosing Chart to help you identify the 2 capsules needed for your prescribed dose. Only use the capsule combinations in the Dosing Chart when your prescribed dose is more than 106 mcg.
- **The capsule must be inhaled within 5 minutes of opening the blister card or the full dose may not be administered. Read through this instruction sheet prior to the first use of this product.**
- Always inhale each capsule 2 times to make sure you get your full dose of YUTREPIA.
- **Do not** wash the inhaler. Keep the inhaler dry.
- Wash and dry your hands before using YUTREPIA.
- If the contents of the capsule comes in contact with your skin or eyes, rinse the area immediately with water.
- YUTREPIA capsules should remain in the blister card(s) and each capsule should be removed only when ready to deliver a dose.

Storing YUTREPIA

- Store YUTREPIA carton in a clean, dry place at room temperature between 68°F to 77°F (20°C to 25°C).
- Leave YUTREPIA capsules in blister card to protect from moisture and light**.**
- Throw away the inhaler after 7 days of use or 56 capsules whichever comes first**.**
- **Keep YUTREPIA and all medicines out of the reach of children.**

Text	**Illustration**
Get to know YUTREPIA	
The YUTREPIA carton contains (See Figure A): • 1 dry powder inhaler (called “inhaler” in these instructions) • 7 Foil blister cards of YUTREPIA capsules (called “capsules” in these instructions) containing 4 capsules each, in one of 4 available strengths • 7 Cleaning brushes (1 for each day) • 1 Desiccant tab within each blister strip to keep the capsule dry and prevent moisture. Throw away the blister strip and the desiccant tab after removing the capsule.	 Figure A
Preparing to use YUTREPIA	
The capsule must be inhaled within 5 minutes of opening the blister card. Ensure all supplies are gathered and you are familiar with the use of the product prior to opening the card. **STEP 1. Gather your supplies.**	 Figure B

a. Place your YUTREPIA carton on a clean, dry surface.
b. Remove the inhaler and foil blister cards from the carton **(See Figure B)**.

STEP 2. Select the capsule(s) for your dose. Use the Dosing Chart **(See Figure C)** to help you identify the capsule(s) needed for your prescribed dose.

- If your prescribed dose is more than 106 mcg, you will need to inhale 2 capsules per the Dosing Chart **(see Figure C)**.
- Only load and inhale 1 capsule at a time.
- All capsules in a carton are the same strength. If your prescribed dose requires 2 capsules of different strengths, you will need to select your capsules from 2 separate cartons.

IMPORTANT: For doses requiring 2 capsules, only use the capsule combinations presented in the Dosing Chart **(See Figure C)**. The order for inhaling 2 capsules does not matter, regardless of capsule strength.

Dose (mcg)	Capsules Needed
26.5	1 Yellow (26.5 mcg)
53	1 Green (53 mcg)
79.5	1 Blue (79.5 mcg)
106	1 Purple (106 mcg)
132.5	1 Green (53 mcg) + 1 Blue (79.5 mcg)
159	2 Blue (79.5 mcg)
185.5	1 Blue (79.5 mcg) + 1 Purple (106 mcg)
212	2 Purple (106 mcg)

Figure C

STEP 3. Check the inhaler and blister card(s).

a. Look at the inhaler and blister card(s) to make sure they are not damaged **(See Figure D)**.
Do not use the inhaler or capsules if they are

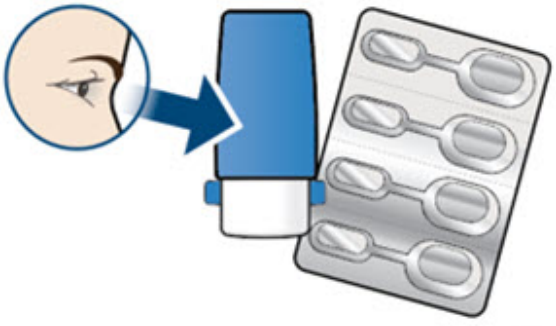


Figure D

damaged.

b. Look at the expiration date on the blister cards to make sure it has not passed **(See Figure E)**. **Do not** use the capsules if the expiration date has passed.

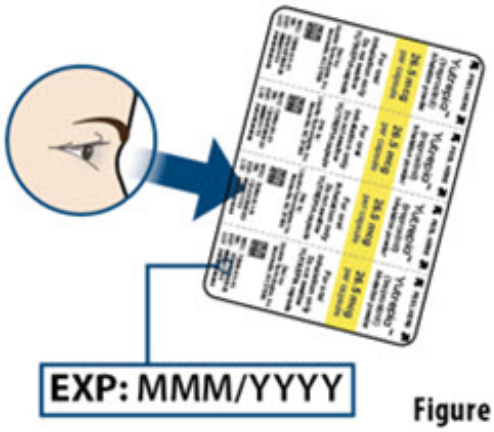


Figure E

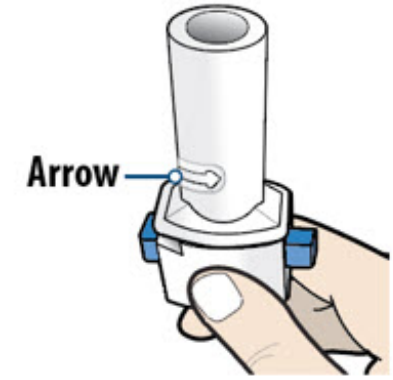
Loading YUTREPIA

STEP 4. Open the inhaler.

a. Pull the cover straight off the inhaler **(See Figure F)**.

b. Rotate the mouthpiece in the direction of the arrow (counter-clockwise) to open the inhaler and expose the capsule chamber **(See Figure G)**.
If the mouthpiece separates from the base of the inhaler, gently reattach the 2 pieces and continue to follow the instructions.


Figure F



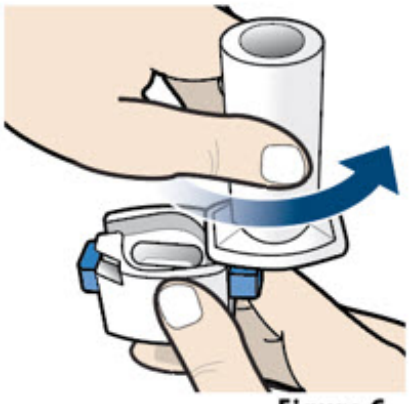


Figure G

STEP 5. Remove the capsule from the blister strip.

a. Separate 1 blister strip by tearing at the pre-cut lines **(See Figure H)**.
Do not remove a capsule from the blister strip until you are ready to deliver your dose.
b. Peel the foil away from the blister strip, remove the capsule **(See Figure I)**.
Do not swallow the capsule.
Do not push the capsule through the foil.
Do not remove the desiccant tab.
Capsule must be used **within 5 minutes** of opening the blister card.

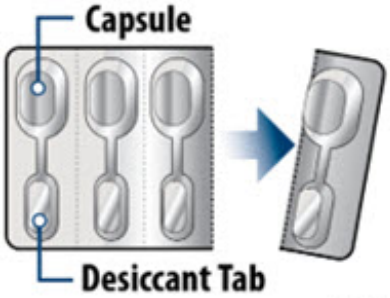


Figure H

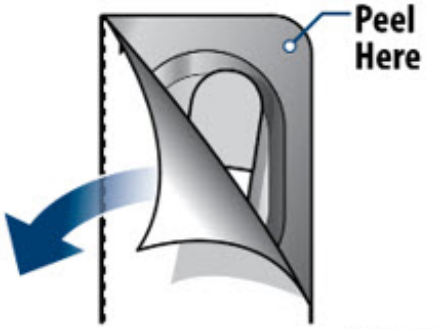


Figure I

STEP 6. Secure the capsule in the inhaler.

a. Hold the inhaler in an upright position.
b. Place the capsule in the capsule chamber in the base of the inhaler **(See Figure J)**. Only load 1 capsule.
Do not place a capsule in the mouthpiece.
Do not swallow capsules.

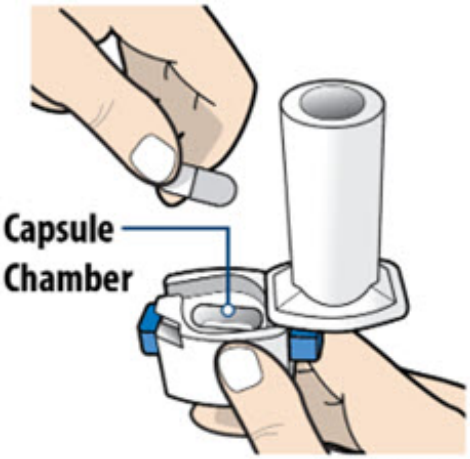


Figure J

STEP 7. Puncture the capsule.

a. Put one finger on top of the capsule to hold it down **(See Figure K)**.
b. While still holding down the capsule, firmly press both puncture buttons all the way in with your

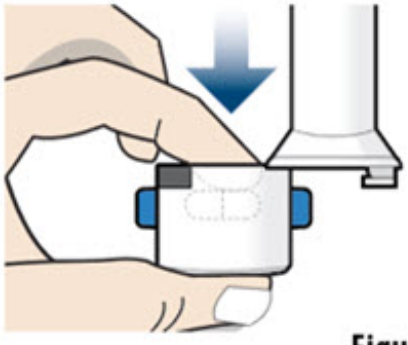
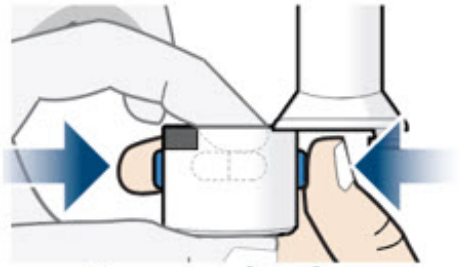
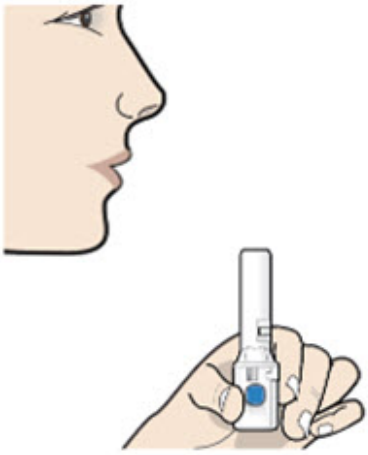


Figure K

other hand **(See Figure L).** Then let go of (release) the puncture buttons. This will puncture the capsule. You only need to press the puncture buttons 1 time. c. Hold the base of the inhaler and rotate the mouthpiece to close it.	 Press and Release Puncture Buttons Figure L
Inhaling YUTREPIA	
STEP 8. Position the inhaler. a. Hold the inhaler upright and away from your mouth. **(See Figure M)**. **Do not** hold the inhaler by the puncture buttons.	 Figure M
STEP 9. Breathe out (exhale). a. Breathe out fully and away from the inhaler **(See Figure N)**. **Do not** exhale into the mouthpiece.	 Figure N

STEP 10. Breathe in deeply (inhale)

a. Close your lips around the mouthpiece **(See Figure O)**.
b. Tilt your head back slightly **(See Figure O)**.
c. Take a comfortable deep breath in (inhale) until your lungs feel full **(See Figure O)**.
As you inhale, you will hear or feel a whirring noise as the capsule spins and releases medicine.

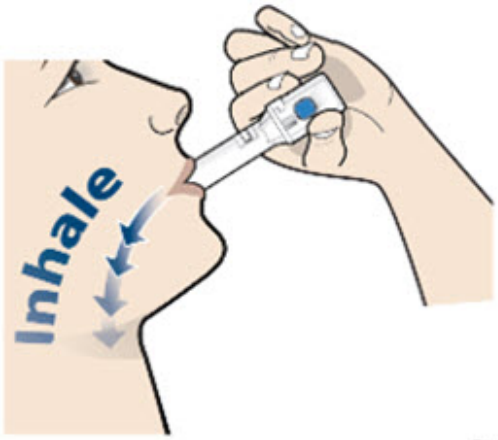


Figure O

STEP 11. Hold breath, then breathe out (exhale).

a. Take the inhaler out of your mouth and hold your breath for 5 seconds or as long as you comfortably can **(See Figure P)**.
b. Then breathe out normally.

IMPORTANT: If you cough when inhaling, repeat STEP 8 through11.

Figure P

STEP 12. Inhale again.

a. To make sure the capsule is completely emptied of medicine, repeat STEP 8 through11 **(See Figure Q)**.
Always inhale each capsule 2 times to make sure you get your full dose.

Figure Q

Removing and disposing of the capsule

STEP 13. Open the inhaler.

a. Rotate the mouthpiece in the direction of the arrow (counter-clockwise) to open the inhaler and expose the capsule chamber **(See Figure R)**.
b. Remove the used (empty) capsule and throw away (dispose of) into household trash **(See Figure S)**.
c. See box below if you need to use more than 1 capsule to complete your prescribed dose.
d. Continue to Step 14 if you have completed your prescribed dose.

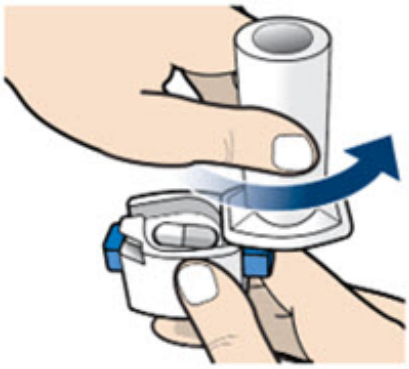


Figure R

Figure S

When dosing with more than one capsule (for doses 132.5 mcg and larger)

If you need to use more than one capsule to complete your prescribed dose, repeat STEP 4 through 13 with each additional capsule.

The order for dosing the capsules does not matter, regardless of capsule strength.

Closing and storing the inhaler

STEP 14. Close the inhaler.

a. Hold the base of the inhaler and rotate the mouthpiece to close it **(See Figure T).**
b. Put the cover on the inhaler **(See Figure U)**.
c. Store the inhaler in a clean, dry place at room temperature.

Figure T

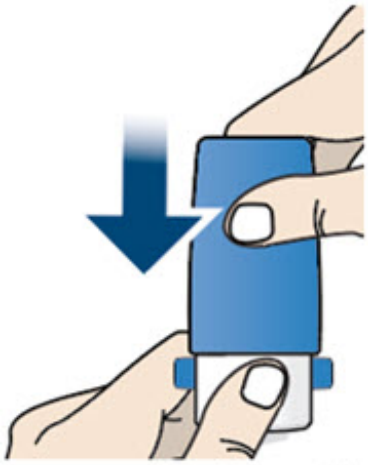


Figure U

Cleaning the inhaler (at end of each day)

Clean the outside and inside of the inhaler after your last dose of the day.

a. Wipe the mouthpiece with a dry paper towel, tissue, or clean dry cloth **(See Figure V)**.
b. Use the cleaning brush provided to clean the capsule chamber in order to remove visible powder buildup **(See Figure W)**. **NOTE:** Throw away the brush after cleaning. Use only 1 brush each day.

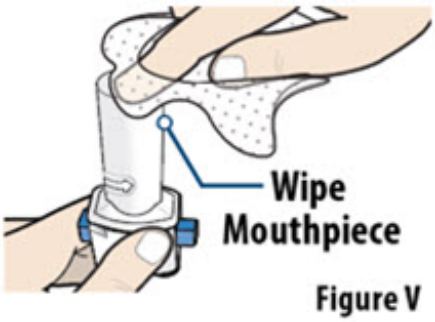


Figure V

Figure W

Disposing of the inhaler

Throw away (dispose of) the inhaler into household trash after 7 days of use.

a. The inhaler is reusable and will last for 7 days (1 week) or 56 capsules, whichever comes first. **(See Figure X)**.

Figure X

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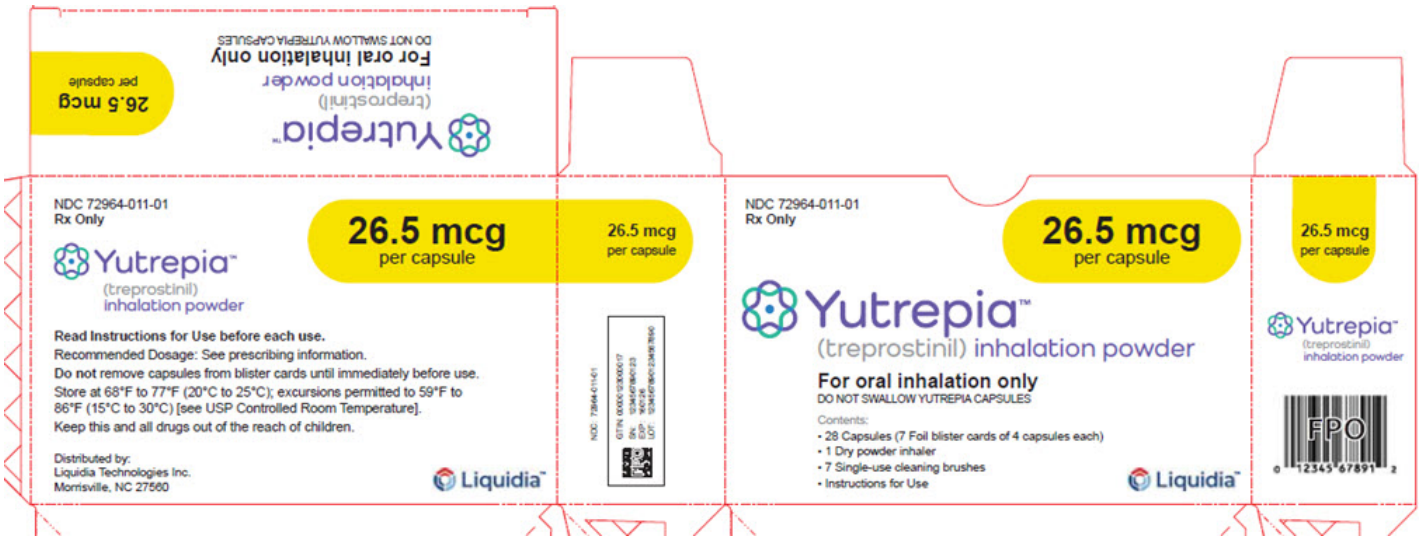
For more information call 1-888-393-LQDA (5732) or go to www.YUTREPIA.com

This Instructions for Use has been approved by the U.S. Food and Drug Administration

Issued: June 2025

PRINCIPAL DISPLAY PANEL – 26.5 mcg Carton



26.5 mcg Carton

NDC 72964-011-01
Rx Only

26.5 mcg
per capsule

Yutrepia™
(treprostinil) inhalation powder

For oral inhalation only
DO NOT SWALLOW YUTREPIA CAPSULES

Contents:

- 28 Capsules (7 Foil blister cards of 4 capsules each)
- 1 Dry powder inhaler
- 7 Single-use cleaning brushes
- Instructions for Use

Liquidia™

NDC 72964-011-01
Rx Only

26.5 mcg
per capsule

Yutrepia™
(treprostinil)
inhalation powder

Read Instructions for Use before each use.
Recommended Dosage: See prescribing information.
Do not remove capsules from blister cards until immediately before use.
Store at 68°F to 77°F (20°C to 25°C); excursions permitted to 59°F to 86°F (15°C to 30°C) [see USP Controlled Room Temperature].
Keep this and all drugs out of the reach of children.

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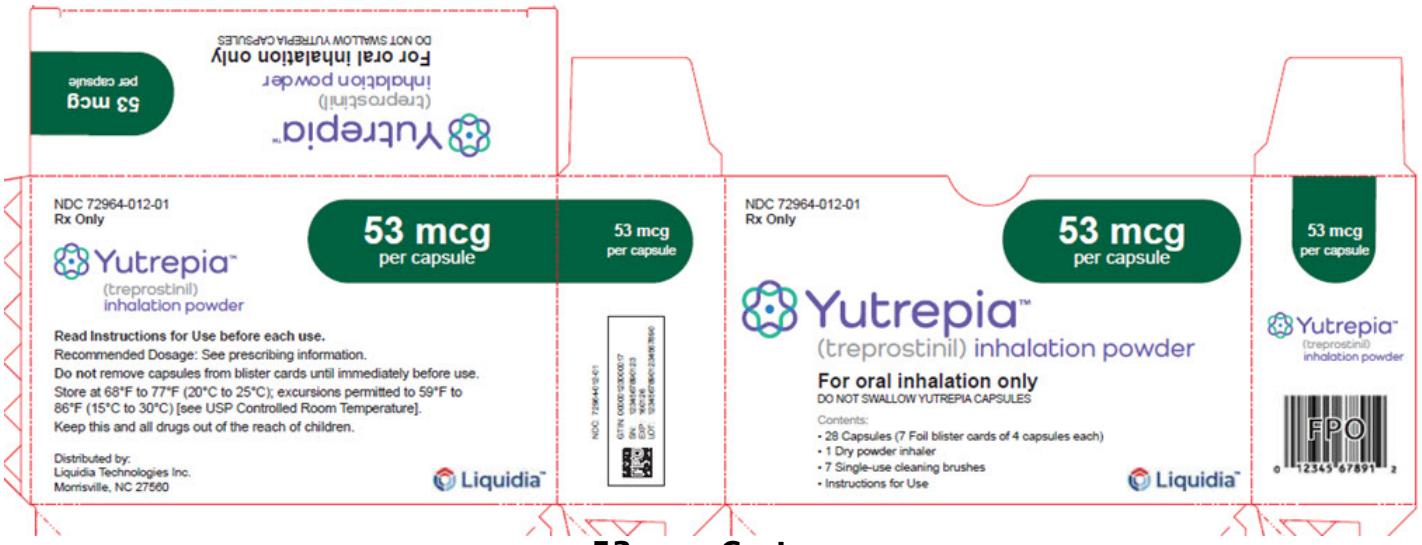
Liquidia™

PRINCIPAL DISPLAY PANEL – 53 mcg Carton



53 mcg Carton

NDC 72964-012-01
Rx Only

53 mcg
per capsule

Yutrepia™
(treprostinil) inhalation powder

For oral inhalation only
DO NOT SWALLOW YUTREPIA CAPSULES

Contents:

- 28 Capsules (7 Foil blister cards of 4 capsules each)
- 1 Dry powder inhaler
- 7 Single-use cleaning brushes
- Instructions for Use

Liquidia™

NDC 72964-012-01
Rx Only

26.5 mcg
per capsule

Yutrepia™
(treprostinil)
inhalation powder

Read Instructions for Use before each use.
Recommended Dosage: See prescribing information.
Do not remove capsules from blister cards until immediately before use.
Store at 68°F to 77°F (20°C to 25°C); excursions permitted to 59°F to 86°F (15°C to 30°C) [see USP Controlled Room Temperature].
Keep this and all drugs out of the reach of children.

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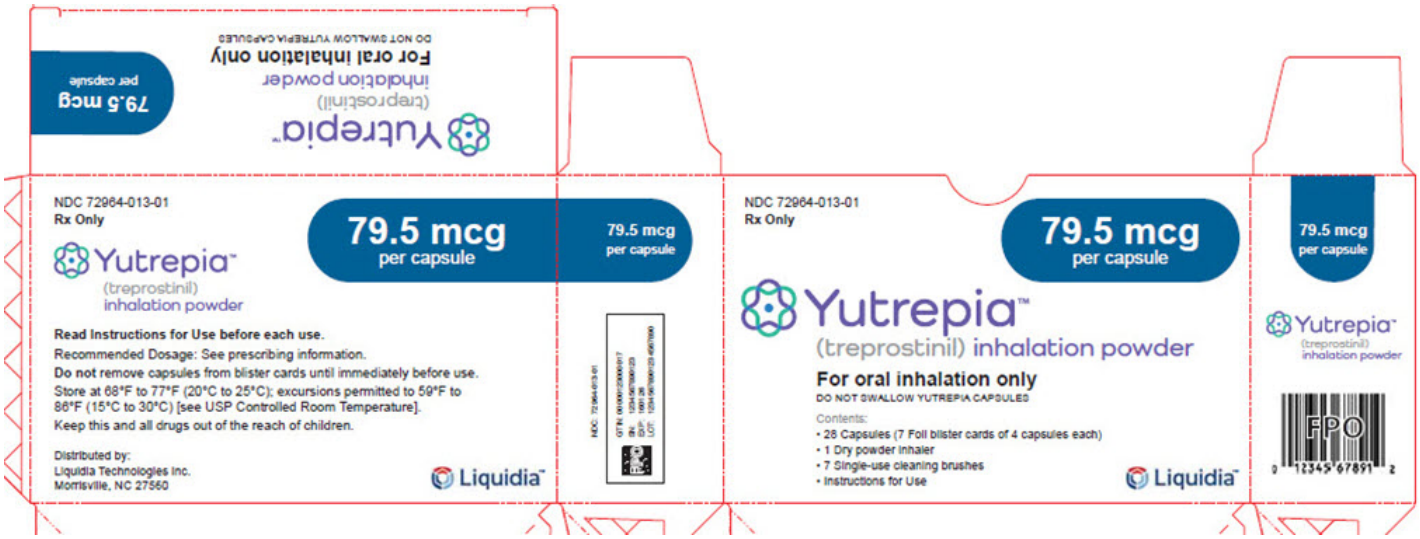
Liquidia™

PRINCIPAL DISPLAY PANEL – 79.5 mcg Carton



79.5 mcg Carton

NDC 72964-013-01

Rx Only

79.5 mcg
per capsule

Yutrepia™
(treprostinil) inhalation powder

For oral inhalation only

DO NOT SWALLOW YUTREPIA CAPSULES

Contents:

- 28 Capsules (7 Foil blister cards of 4 capsules each)
- 1 Dry powder inhaler
- 7 Single-use cleaning brushes
- Instructions for Use

Liquidia™

NDC 72964-013-01
Rx Only

79.5 mcg
per capsule

Yutrepia™
(treprostinil)
inhalation powder

Read Instructions for Use before each use.
Recommended Dosage: See prescribing information.
Do not remove capsules from blister cards until immediately before use.
Store at 68°F to 77°F (20°C to 25°C); excursions permitted to 59°F to 86°F (15°C to 30°C) [see USP Controlled Room Temperature].
Keep this and all drugs out of the reach of children.

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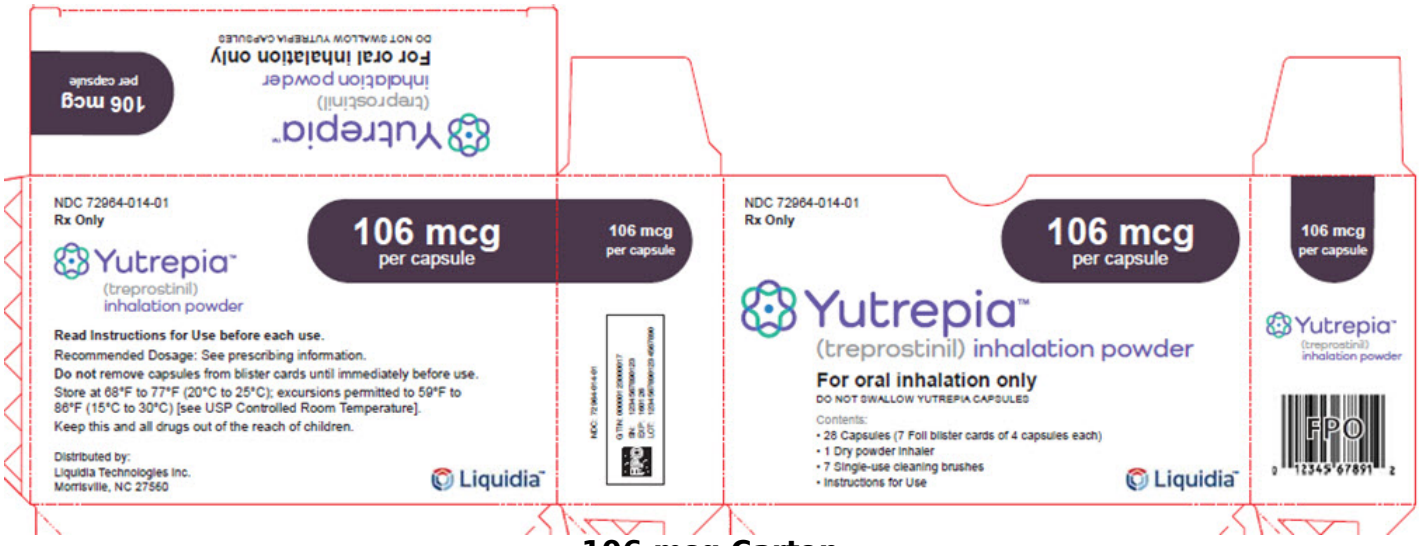
Liquidia™

PRINCIPAL DISPLAY PANEL – 106 mcg Carton



106 mcg Carton

NDC 72964-014-01
Rx Only

106 mcg
per capsule

Yutrepia™
(treprostinil) inhalation powder

For oral inhalation only
DO NOT SWALLOW YUTREPIA CAPSULES

Contents:

- 28 Capsules (7 Foil blister cards of 4 capsules each)
- 1 Dry powder inhaler
- 7 Single-use cleaning brushes
- Instructions for Use

Liquidia™

NDC 72964-014-01
Rx Only

106 mcg
per capsule

Yutrepia™
(treprostinil)
inhalation powder

Read Instructions for Use before each use.
Recommended Dosage: See prescribing information.
Do not remove capsules from blister cards until immediately before use.
Store at 68°F to 77°F (20°C to 25°C); excursions permitted to 59°F to 86°F (15°C to 30°C) [see USP Controlled Room Temperature].
Keep this and all drugs out of the reach of children.

Distributed by:
Liquidia Technologies Inc.
Morrisville, NC 27560

Liquidia™

YUTREPIA
treprostinil capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72964-011
Route of Administration	RESPIRATORY (INHALATION)		

Active Ingredient/Active Moiety		

Ingredient Name	Basis of Strength	Strength
TREPROSTINIL SODIUM (UNII: 7JZ75N2NT6) (TREPROSTINIL - UNII:RUM6K67ESG)	TREPROSTINIL	26.5 ug

Inactive Ingredients

Ingredient Name	Strength
TREHALOSE DIHYDRATE (UNII: 7YIN7J07X4)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
LEUCINE (UNII: GMW67QNF9C)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Product Characteristics

Color	YELLOW	**Score**	no score
Shape	CAPSULE	**Size**	16mm
Flavor		**Imprint Code**	LIQUIDIA;26;5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72964-011-01	7 in 1 CARTON	05/23/2025	
1		4 in 1 BLISTER PACK		
1		1 in 1 CAPSULE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA213005	05/23/2025	

YUTREPIA

treprostinil capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72964-012
Route of Administration	RESPIRATORY (INHALATION)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TREPROSTINIL SODIUM (UNII: 7JZ75N2NT6) (TREPROSTINIL - UNII:RUM6K67ESG)	TREPROSTINIL	53 ug

Inactive Ingredients	
Ingredient Name	**Strength**
TREHALOSE DIHYDRATE (UNII: 7YIN7J07X4)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
LEUCINE (UNII: GMW67QNF9C)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Product Characteristics			
Color	GREEN	**Score**	no score
Shape	CAPSULE	**Size**	16mm
Flavor		**Imprint Code**	LIQUIDIA;53
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:72964-012-01	7 in 1 CARTON	05/23/2025	
1		4 in 1 BLISTER PACK		
1		1 in 1 CAPSULE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA213005	05/23/2025	

YUTREPIA

treprostinil capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72964-013
Route of Administration	RESPIRATORY (INHALATION)		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TREPROSTINIL SODIUM (UNII: 7JZ75N2NT6) (TREPROSTINIL - UNII:RUM6K67ESG)	TREPROSTINIL	79.5 ug

Inactive Ingredients

Ingredient Name	Strength
TREHALOSE DIHYDRATE (UNII: 7YIN7J07X4)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
LEUCINE (UNII: GMW67QNF9C)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Product Characteristics

Color	BLUE	**Score**	no score
Shape	CAPSULE	**Size**	16mm
Flavor		**Imprint Code**	LIQUIDIA;79;5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72964-013-01	7 in 1 CARTON	05/23/2025	
1		4 in 1 BLISTER PACK		
1		1 in 1 CAPSULE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA213005	05/23/2025	

YUTREPIA

treprostinil capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72964-014
Route of Administration	RESPIRATORY (INHALATION)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TREPROSTINIL SODIUM (UNII: 7JZ75N2NT6) (TREPROSTINIL - UNII:RUM6K67ESG)	TREPROSTINIL	106 ug

Inactive Ingredients

Ingredient Name	Strength
TREHALOSE DIHYDRATE (UNII: 7YIN7J07X4)	

POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
LEUCINE (UNII: GMW67QNF9C)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Product Characteristics

Color	PURPLE	**Score**	no score
Shape	CAPSULE	**Size**	16mm
Flavor		**Imprint Code**	LIQUIDIA;106
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72964-014-01	7 in 1 CARTON	05/23/2025	
1		4 in 1 BLISTER PACK		
1		1 in 1 CAPSULE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA213005	05/23/2025	

Labeler - Liquidia Technologies, Inc. (157103164)

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