RAPIBLYK- landiolol injection, powder, lyophilized, for solution
AOP Orphan Pharmaceuticals GmbH

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

RAPIBLYK (landiolol) for injection, for intravenous use
Initial U.S. Approval: 2024

RECENT MAJOR CHANGES

Below section were updated with Pediatric Patients
Indications and Usage (1) 2/2026
Dosage and Administration (2.1) 2/2026

INDICATIONS AND USAGE

RAPIBLYK is a beta adrenergic blocker indicated for the short-term reduction of ventricular rate in: adults with supraventricular tachycardia including atrial fibrillation and atrial flutter (1), and pediatric patients with supraventricular tachycardia.(1)

DOSAGE AND ADMINISTRATION

- Administer as an intravenous infusion in a monitored setting. (2.1)
- Titrate according to ventricular rate. (2.1)
- If normal cardiac function, start at 9 mcg/kg/min; adjust dose in 10-minute intervals as needed in increments of 9 mcg/kg/min to a maximum of 36 mcg/kg/min. (2.1)
- If impaired cardiac function, start at 1 mcg/kg/min; adjust dose in 15-minute intervals as needed in increments of 1 mcg/kg/min to a maximum of 36 mcg/kg/min. (2.1).

DOSAGE FORMS AND STRENGTHS

For injection: 280 mg of landiolol (equivalent to 300 mg of landiolol HCl) as a lyophilized powder in a single-dose vial. (3)

CONTRAINDICATIONS

- 5.3Severe sinus bradycardia (4)
- Sick sinus syndrome (4)
- Heart block greater than first degree (4)
- Decompensated heart failure (4)
- Cardiogenic shock (4)
- Pulmonary hypertension (4)
- Known hypersensitivity to landiolol (4)

WARNINGS AND PRECAUTIONS

- Risk of hypotension, bradycardia, and cardiac failure: Monitor for signs and symptoms of cardiovascular adverse effects. Reduce or discontinue use (5.1, 5.2, 5.3)
- Risk of exacerbating reactive airway disease (5.4)
- Diabetes mellitus: May mask symptoms of hypoglycemia and alter glucose levels; monitor (5.5)
- Monitor for signs of myocardial ischemia when abruptly discontinuing in patients with coronary artery disease (5.10)

ADVERSE REACTIONS

The most common adverse reaction (9.9%) is hypotension (6.1).
To report SUSPECTED ADVERSE REACTIONS, contact AOP Orphan Pharmaceuticals at ICSR@aop-health.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Negative Inotropes and Chronotropes: Avoid (7.1)
- Sympathomimetics, Positive Inotropes and Vasoconstrictors: Avoid (7.2)
- Catecholamine Depleting Drugs: Monitor blood pressure and heart rate (7.3).

Revised: 10/2026

FULL PRESCRIBING INFORMATION: CONTENTS*

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

RAPIBLYK is indicated for the short-term reduction of ventricular rate in

- adults with supraventricular tachycardia including atrial fibrillation and atrial flutter, and
- pediatric patients with supraventricular tachycardia.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage

Administer RAPIBLYK as a continuous intravenous infusion in a monitored setting, titrating as needed for heart rate control. There are limited data beyond 24 hours of use.

	Adults		**Pediatric patients**
	Normal cardiac function	**Impaired cardiac function**	**Normal cardiac function***
Starting dose	9 mcg/kg/min	1 mcg/kg/min	9 mcg/kg/min
Titration interval	10 min	15 min	10 min
Titration step	9 mcg/kg/min	1 mcg/kg/min	9 mcg/kg/min
Maximum dose	36 mcg/kg/min	36 mcg/kg/min	36 mcg/kg/min

*There are no data to guide dosage recommendations in pediatric patients with impaired cardiac function.

2.2 Transitioning from RAPIBLYK Injection Therapy to Alternative Medications

When transitioning to alternative medications consider the pharmacodynamics of the medication to which the patient is being transitioned and monitor clinical response. If switched to an oral beta-blocker, the dosage of RAPIBLYK can be reduced as follows:

- Ten minutes after administration of the oral beta-blocker, reduce the infusion rate of RAPIBLYK by 50%.
- If satisfactory control is maintained for at least one hour, discontinue RAPIBLYK.

2.3 Instructions for Preparation

- Use appropriate aseptic technique for reconstitution.
- Reconstitute each 280 mg vial of RAPIBLYK with 50 mL of 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP. Gently swirl to dissolve contents.
- Inspect parenteral drug products for particulate matter and discoloration prior to administration, whenever solution and container permit. The reconstituted solution should be a clear, colorless solution.
- Use immediately. The reconstituted RAPIBLYK solution storage conditions are described in Table 2.
- Discard unused portion.

Table 2: Reconstituted RAPIBLYK Solution Storage and Use Conditions

Diluent used to Prepare Solution	**Reconstituted RAPIBLYK Solution Storage and Use Conditions**
50 mL of 0.9% Sodium Chloride Injection, USP	Use within 4 hours at room temperature (25°C, 77°F)
50 mL of 5% Dextrose Injection, USP	Use within 48 hours at room temperature (25°C, 77°F)

2.4 Administration

Following reconstitution, the product contains 280 mg landiolol/50 mL = 5.6 mg/mL.

The infusion rate can be calculated as:
- Infusion rate (mL/hour) = target dose (mcg/kg/min) × body weight (kg) / 93

3 DOSAGE FORMS AND STRENGTHS

For injection: White to almost white lyophilized powder in a single-dose vial containing 280 mg of landiolol (equivalent to 300 mg landiolol HCl).

4 CONTRAINDICATIONS

RAPIBLYK is contraindicated in patients with:
- Severe sinus bradycardia, sick sinus syndrome, heart block greater than first degree *[see Warnings and Precautions (*5.2*)]*.
- Decompensated heart failure *[see Warnings and Precautions (*5.3*)]*.
- Cardiogenic shock: May precipitate further cardiovascular collapse and cause cardiac arrest.
- Pulmonary hypertension: May precipitate cardiorespiratory decompensation.
- Hypersensitivity reactions, including anaphylaxis, to landiolol or any of the inactive ingredients

5 WARNINGS AND PRECAUTIONS

5.1 Hypotension

Patients with hemodynamic compromise, hypovolemia, or on interacting medications are at increased risk of hypotension. Monitor blood pressure closely, especially if

pretreatment blood pressure is low. Reduce or stop RAPIBLYK injection for hypotension then expect the blood pressure effect to wane within 30 minutes.

5.2 Bradycardia

Patients with first-degree atrioventricular block, sinus node dysfunction, or conduction disorders are at increased risk of bradycardia, including sinus pause, heart block, severe bradycardia, and cardiac arrest. Monitor heart rate and rhythm in patients receiving RAPIBLYK injection. Reduce or stop RAPIBLYK injection for bradyarrhythmia.

5.3 Cardiac Failure

Beta-blockers, like RAPIBLYK, can cause depression of myocardial contractility and may precipitate heart failure and cardiogenic shock. At the first sign or symptom of impending cardiac failure, stop RAPIBLYK injection and start supportive therapy *[see Overdosage (*10*)]*.

5.4 Reactive Airways Disease

Patients with reactive airways disease should, in general, not receive beta-blockers. Because of its relative beta-1 selectivity and titratability, RAPIBLYK injection may be titrated to the lowest possible effective dose. In the event of bronchospasm, stop the infusion immediately; a beta-2 stimulating agent may be administered with appropriate monitoring of ventricular rates.

5.5 Use in Patients with Diabetes Mellitus and Hypoglycemia

Beta-blockers may prevent early warning signs of hypoglycemia, such as tachycardia, and increase the risk for severe or prolonged hypoglycemia at any time during treatment, especially in patients with diabetes mellitus, patients who are fasting (i.e., surgery, not eating regularly, or are vomiting), or pediatric patients. Monitor for signs and symptoms of hypoglycemia in patients receiving RAPIBLYK.

5.6 Infusion Site Reactions

Infusion site reactions such as pain, swelling and erythema have occurred with the use of RAPIBLYK injection. Avoid infusions into small veins or through a butterfly catheter. If a local infusion site reaction develops, use an alternative infusion site and avoid extravasation.

5.7 Use in Patients with Prinzmetal’s Angina

Beta-blockers may exacerbate anginal attacks in patients with Prinzmetal’s angina because of unopposed alpha receptor–mediated coronary artery vasoconstriction.

5.8 Use in Patients with Pheochromocytoma

If RAPIBLYK injection is used in the setting of pheochromocytoma, administer RAPIBLYK in combination with an alpha-blocker, and only after the alpha-blocker has been initiated. Administration of beta-blockers without opposing alpha blockade in the setting of pheochromocytoma has been associated with a paradoxical increase in blood pressure from the attenuation of beta receptor-mediated vasodilation in skeletal muscle.

5.9 Use in Patients with Peripheral Circulatory Disorders

RAPIBLYK injection may exacerbate peripheral circulatory disorders, such as Raynaud's disease or syndrome, and peripheral occlusive vascular disease.

5.10 Abrupt Discontinuation of RAPIBLYK Injection

Severe exacerbations of angina, myocardial infarction, and ventricular arrhythmias have been reported in patients with coronary artery disease upon abrupt discontinuation of beta-blocker therapy. Observe patients for signs of myocardial ischemia when discontinuing RAPIBLYK injection.

5.11 Hyperkalemia

Beta-blockers, including RAPIBLYK injection, can cause increases in serum potassium and hyperkalemia. The risk is increased in patients with risk factors such as renal impairment. Intravenous administration of beta-blockers has been reported to cause potentially life-threatening hyperkalemia in hemodialysis patients. Monitor serum electrolytes during therapy with RAPIBLYK injection.

5.12 Use in Patients with Metabolic Acidosis

Beta-blockers have been reported to cause hyperkalemic renal tubular acidosis. Acidosis in general may be associated with reduced cardiac contractility.

5.13 Use in Patients with Hyperthyroidism

Beta-adrenergic blockade may mask certain clinical signs (e.g., tachycardia) of hyperthyroidism. Abrupt withdrawal of beta blockade might precipitate thyroid storm; therefore, monitor patients for signs of thyrotoxicosis when withdrawing beta blocking therapy.

5.14 Use in Patients at Risk of Severe Acute Hypersensitivity Reactions

When using beta-blockers, patients at risk of anaphylactic reactions may be more reactive to allergen exposure (accidental, diagnostic, or therapeutic).

Patients using beta-blockers may be unresponsive to the usual doses of epinephrine used to treat anaphylactic or anaphylactoid reactions *[see Drug Interactions (7)]*.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, the 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 clinical practice.

The safety of RAPIBLYK was evaluated in 19 placebo-controlled clinical trials involving 1,761 adult patients (in a variety of clinical in-patient settings) with supraventricular tachycardia or at high risk for supraventricular tachycardia. The most common adverse reaction is hypotension, which occurred in 9.9% of patients receiving RAPIBLYK vs. 1%

in those receiving placebo [see Warnings and Precautions (5.1)].

In a single-arm, unblinded clinical trial in 60 pediatric patients who received RAPIBLYK, the most common adverse reaction was hypotension, which occurred in 10% of patients aged birth to <18 years receiving RAPIBLYK [see Warnings and Precautions (5.1)]. Hypotension was also the most common adverse reaction leading to treatment discontinuation.

7 DRUG INTERACTIONS

7.1 Negative Inotropes and Chronotropes

Avoid concomitant use of RAPIBLYK with negative inotropes and medications that slow heart rate or cardiac conduction.

Beta-blockers, like RAPIBLYK, can cause depression of myocardial contractility and increase the risk of bradycardia or heart block. Concomitant use of RAPIBLYK with negative inotropes or chronotropes may augment these effects *[see Warnings and Precautions (*5.2*,* 5.3*)]*.

7.2 Sympathomimetics, Positive Inotropes and Vasoconstrictors

Beta adrenergic agonists will antagonize the effects of RAPIBLYK and may attenuate the heart rate lowering effects of RAPIBLYK. Positive inotropes and vasoconstrictors may attenuate the heart rate and blood pressure lowering effects of RAPIBLYK.

7.3 Catecholamine Depleting Drugs

Observe patients treated with RAPIBLYK plus a catecholamine depletor (e.g., reserpine, monoamine oxidase inhibitors) for hypotension or marked bradycardia, which may cause vertigo, syncope, or postural hypotension.

Catecholamine depleting drugs may have an additive effect when given with beta-blockers, which may increase the risk of hypotension or marked bradycardia related vertigo, syncope, or postural hypotension *[see Warnings and Precautions (*5.1*)]*.

8 USE IN SPECIFIC POPULATIONS

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8.1 Pregnancy

Risk Summary

The available published data on RAPIBLYK use in pregnant women are insufficient to inform a drug associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes. Landiolol exposure was limited to a single injection at the time of Cesarean delivery in a small clinical trial. Neonatal bradycardia, hypoglycemia, and respiratory depression have been observed with use of beta-blockers in pregnancy near the time of delivery *(see Clinical Considerations)*. Administration of landiolol to pregnant rats showed distribution of landiolol to the placenta and the fetus. In animal reproduction studies, no embryo-fetal toxicity was observed in rats or rabbits during the period of organogenesis at landiolol exposure in rats approximately 2.7 times human exposure at

the maximum recommended human dose (MRHD) *(see Data)*.

The background risk of major birth defects and miscarriage for the indicated population 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

Fetal/Neonatal Adverse Reactions

Landiolol crosses the placenta in rats. Neonates born to mothers who are receiving landiolol during pregnancy, may be at risk for hypotension, hypoglycemia, bradycardia, and respiratory depression. Monitor neonates exposed to landiolol during pregnancy and labor for hypotension, hypoglycemia, bradycardia, and respiratory depression and manage accordingly.

Data

Animal Data

Landiolol HCl was administered intravenously to pregnant rats (25, 50, or 100 mg/kg/day from gestation day 7 to 17) and rabbits (25, 50, or 100 mg/kg/day from gestation day 8 to 18). No adverse embryo-fetal effects were observed in rats at the landiolol HCl dose of 25 mg/kg/day, resulting in systemic landiolol exposure (AUC) of approximately 2.7-times the exposure at the MRHD. In rabbits, no adverse embryo-fetal effects were detected at the landiolol HCl dose of 100 mg/kg/day; the resulting systemic landiolol exposure (AUC) at this dose level was not determined.

In a prenatal and postnatal development study in rats, landiolol HCl was administered intravenously at 25, 50, or 100 mg/kg/day from gestation day 17 to postpartum/lactation day 20. A decrease in the viability index for the offspring on postpartum day 4 was observed for the high dose group. No effect on pre/post-natal development was observed at 50 mg/kg dose, which represents landiolol exposures approximately 5.4 times the human exposure at the MRHD.

8.2 Lactation

Risk Summary

There are no data on the presence of landiolol and its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production. However, other drugs in this class are detected in human milk.

Landiolol was present in the milk of lactating rats *(see Data)*. When a drug is present in animal milk, it is likely that the drug will be present in human milk, but the concentration of landiolol in animal milk does not necessarily predict the concentration of drug in human milk.

The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for RAPIBLYK and any potential adverse effects on the breastfed infant from RAPIBLYK or from the underlying maternal condition.

Clinical Considerations

Monitoring for adverse reactions

Monitor the breastfed infant for bradycardia and other symptoms of beta blockade, such as lethargy (hypoglycemia).

Data

In a lactation study, administration of ^{14}C-landiolol HCl administered as a single 1 mg/kg intravenous injection to lactating rats on postpartum/lactation day 13 to 14 was excreted in milk corresponding to approximately 70% of the concentration in plasma.

8.4 Pediatric Use

The safety and effectiveness of RAPIBLYK for the short-term reduction of ventricular rate in supraventricular tachycardia have been established in pediatric patients. Use of RAPIBLYK is supported by evidence from adequate and well-controlled studies in adults, with additional pharmacokinetic, pharmacodynamic and safety data from a descriptive single-arm, unblinded study that enrolled 60 pediatric patients from birth to <18 years of age. In this study, treatment with RAPIBLYK resulted in a >20% reduction in ventricular rate from baseline in patients with atrioventricular reentrant tachycardia (6/7, 85.7%), focal atrial tachycardia (4/8, 50%), junctional ectopic tachycardia (3/12, 25%), and in inappropriate sinus tachycardia (10/30, 33.3%) [see Clinical Pharmacology (12.3)].

8.5 Geriatric Use

Clinical studies of RAPIBLYK did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. In general, dose selection for an elderly patient should usually start at the low end of the dosing range, reflecting greater frequency of decreased renal or cardiac function and of concomitant disease or other drug therapy.

8.6 Hepatic Impairment

More conservative dose titration is recommended in patients with mild hepatic impairment (Child-Pugh A). The effect of moderate or severe hepatic impairment (Child-Pugh B or C) on landiolol pharmacokinetics is unknown. Avoid use of RAPIBLYK in patients with moderate or severe hepatic impairment (Child-Pugh B or C). *[see Clinical Pharmacokinetics (*12.3*)]*.

10 OVERDOSAGE

10.1 Signs and Symptoms of Overdose

Overdoses of RAPIBLYK injection can cause adverse cardiac and central nervous system effects. These adverse effects may precipitate severe signs, symptoms, sequelae, and complications such as severe cardiac and respiratory failure, including shock and coma, and may be fatal. Continuous monitoring of the patient is required.

- Cardiac adverse effects include bradycardia, atrioventricular block (1-, 2-, 3-degree), junctional rhythms, intraventricular conduction delays, decreased cardiac contractility, hypotension, cardiac failure (including cardiogenic shock), cardiac arrest/asystole, and pulseless electrical activity.
- Central nervous system adverse effects include respiratory depression, seizures,

sleep and mood disturbances, fatigue, lethargy, and coma.
- In addition, bronchospasm, hyperkalemia, and hypoglycemia (especially in pediatric patients) may occur.

10.2 Treatment Recommendations

Because of its approximately 4-minute elimination half-life, the first step in the management of toxicity should be to discontinue RAPIBLYK infusion. Then, based on the observed clinical effects, consider the following general measures:

Bradycardia

Consider intravenous administration of atropine or another anticholinergic drug or cardiac pacing.

Cardiac Failure

Consider intravenous administration of a diuretic or digitalis glycoside. In shock resulting from inadequate cardiac contractility, consider intravenous administration of dopamine, dobutamine, isoproterenol, milrinone or inamrinone.

Symptomatic Hypotension

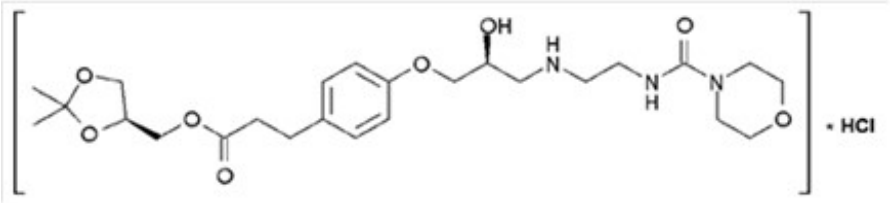
Consider intravenous administration of fluids or vasopressor agents such as dopamine or norepinephrine.

Bronchospasm

Consider intravenous administration of a beta agonist or a theophylline derivative.

11 DESCRIPTION

RAPIBLYK (landiolol) for injection is a beta-1 adrenergic receptor blocker with a very short duration of action (elimination half-life is approximately 4 minutes). Landiolol is:
- [(4S)-2,2-dimethyl-1,3-dioxolan-4-yl]methyl 3-[4-[(2S)-2-hydroxy-3-[2-(morpholine-4-carbonylamino)ethylamino]propoxy]phenyl]propionate and has the following structure:



- The active pharmaceutical ingredient is the hydrochloride salt of landiolol, which has the empirical formula $C_{25}H_{39}N_3O_8$ • HCl and a molecular weight of 546.06 g/mol. It has two chiral centers and is used as pure S,S-enantiomer.
- Landiolol HCl is a white crystalline powder. It is a relatively hydrophilic compound, which is very soluble in water.

RAPIBLYK is supplied as a single presentation of 280 mg landiolol (equivalent to 300 mg landiolol HCl) as a white to almost white sterile lyophilized powder for intravenous injection in a single-dose vial. Inactive ingredients include 300 mg of mannitol and sodium hydroxide as needed to adjust pH.

12 CLINICAL PHARMACOLOGY

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12.1 Mechanism of Action

RAPIBLYK is a selective beta-1-adrenoreceptor antagonist that inhibits the positive chronotropic effects of the catecholamines, epinephrine and norepinephrine, on the heart, where beta-1-receptors are predominantly located. Landiolol does not exhibit any membrane-stabilizing activity or intrinsic sympathomimetic activity at the approved recommended dosage in vitro.

12.2 Pharmacodynamics

Landiolol exposure-response relationships and the time course of pharmacodynamic response are not fully characterized.

12.3 Pharmacokinetics

Landiolol peak plasma concentration (C_{max}) over the approved dosage range in healthy adult volunteers, patients with atrial fibrillation or atrial flutter and pediatric patients with supraventricular tachycardia is provided in Table 3.

Table 3: Landiolol peak plasma concentration (Cmax) in healthy volunteers and patients with atrial fibrillation or atrial flutter.

	Peak Plasma Concentration (C_{max})		
Landiolol Dosage	**Healthy Adult Volunteers (mean) [a]**	**Adult Patients with Atrial Fibrillation or Atrial Flutter (range)**	**Pediatric Patients with Supraventricular Tachycardia (range)**
9.3 mcg/kg/min	0.2 mcg/mL	Not studied	Not available
18.6 mcg/kg/min	0.5 mcg/mL	Not studied	Not available
37.3 mcg/kg/min	1.0 mcg/mL	0.52 to 1.77 mcg/mL	0.52 to 4.71 mcg/mL

[a] 2 hour infusion

9.3 mcg/kg/min landiolol is equivalent to 10 mcg/kg/min landiolol hydrochloride.

Landiolol pharmacokinetics increases dose-proportionally in the dosage range of 9.3 to 74.6 mcg/kg/min (2 times the maximum approved recommended dosage). Landiolol reached steady-state values approximately 15 minutes after initiation of the infusion.

Distribution

Landiolol steady state volume of distribution is 0.4 L/kg. Landiolol protein binding is <10%.

Elimination

Landiolol elimination half-life is 4.5 minutes at steady state. Total body clearance of

landiolol is 57 mL/kg/min following a 20-hour continuous landiolol infusion of 37.3 mcg/kg/min.

Metabolism

Landiolol is primarily metabolized by pseudocholinesterases and carboxylesterases in the plasma to the active metabolite M1.

M1 has less than 1/40 th of the pharmacological activity of landiolol. M1 AUC $_{0\text{-inf}}$ is approximately 12 times greater than landiolol.

Excretion

Approximately 50 to 75% of the landiolol administered dose (approximately half of this as metabolite M1, and 8% as parent) is recovered in urine at 4 hours and 89 to 99% at 24 hours following a 60 min intravenous infusion.

Specific Populations

The effect of age and renal impairment on landiolol pharmacokinetics is unknown.

Patients with hepatic impairment

Landiolol geometric mean AUC increased by 44% and C $_{max}$ by 42% in 5 patients with mild hepatic impairment (Child-Pugh A) and 1 patient with moderate hepatic impairment (Child-Pugh B). The effect of moderate hepatic impairment (Child-Pugh B) on landiolol pharmacokinetics has not been fully characterized and the effect of severe hepatic impairment (Child-Pugh C) is unknown.

Drug Interaction Studies

In Vitro Studies

CYP 450 enzymes: Landiolol and the metabolite M1 are time-dependent CYP 2D6 inhibitors at exposures approximately 50 times the human exposure at the MRHD, but do not inhibit CYP 1A2, 2C9, 2C19, or 3A4.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Animal studies have not been conducted to evaluate the carcinogenic potential of RAPIBLYK.

Mutagenesis

Landiolol was not genotoxic when tested in a battery of assays (Ames, in vitro mouse lymphoma TK $^{+/-}$, and in vivo micronucleus test in rats).

Impairment of Fertility

No adverse effects on fertility were observed in male and female rats administered a landiolol HCl dose of 100 mg/kg/day, resulting in systemic exposure (AUC) approximately 10-times the exposure at the MRHD

14 CLINICAL STUDIES

In 5 randomized, double-blind, placebo-controlled studies, treatment of 317 adults with supraventricular tachycardia with landiolol decreased heart rate in 40-90% of treated patients within about 10 minutes, compared to 0-11% of patients who received placebo; heart rate decrease was defined as a >20% decrease in heart rate or a heart rate <100 bpm or at least intermittent cessation of the arrhythmia. The infused dose of landiolol in these studies ranged from 9.3 to 74.6 mcg/kg/min (equivalent to 10 to 80 mcg/kg/min landiolol hydrochloride).

16 HOW SUPPLIED/STORAGE AND HANDLING

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16.1 How Supplied

RAPIBLYK is supplied as a white to almost white, preservative-free, lyophilized powder in single dose vials containing 280 mg landiolol for injection (equivalent to 300 mg landiolol HCl).

Each vial is supplied in a carton NDC 84381-110-01

16.2 Storage

Store unreconstituted product at 20°C to 25°C (68ºF to 77ºF) [see USP Controlled Room Temperature], with excursions permitted to 15ºC to 30ºC (59ºF to 86ºF). Store in the original carton to protect from light.

Manufactured for:

AOP Orphan Pharmaceuticals GmbH

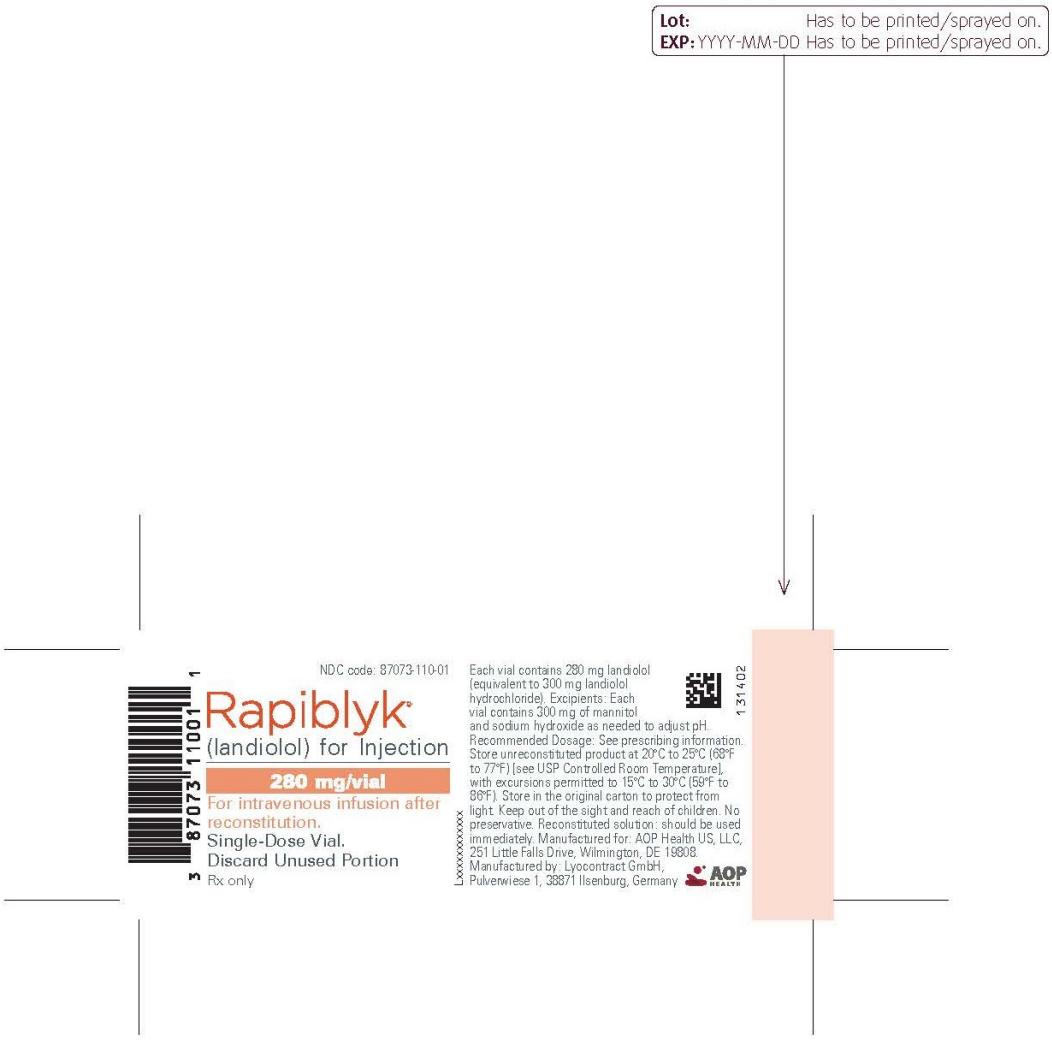
Leopold-Ungar-Platz 2

1190 Vienna

Austria

Part number/

GTIN: 00387073110011	Has to be printed/sprayed on.
SN:	Has to be printed/sprayed on.
Lot:	Has to be printed/sprayed on.
EXP: YYYY-MM-DD	Has to be printed/sprayed on.
Data Matrix Code:	Has to be printed/sprayed on.



RAPIBLYK

landiolol injection, powder, lyophilized, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:84381-110
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LANDIOLOL HYDROCHLORIDE (UNII: G8HQ634Y17) (LANDIOLOL - UNII:62NWQ924LH)	LANDIOLOL	280 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
MANNITOL (UNII: 3OWL53L36A)	300 mg

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:84381-110-01	1 in 1 CARTON	08/07/2025	
1		1 in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA217202	08/07/2025	

Labeler - AOP Orphan Pharmaceuticals GmbH (300757940)

Revised: 10/2026 AOP Orphan Pharmaceuticals GmbH