Lopressor®
(Metoprolol Tartrate)
Oral Solution
10 mg/mL

Validus Patient Application: Authorization for Services

Phone: 886-524-6546 Fax: 877-256-2430

LIQUID™ Innovation with care
Validus Patient Support Program

Please complete this form and fax them to Validus Liquid Innovation with Care Patient Support via the number above.

Prescribing Physician Information

Name (First, Last) _____ Site Name _____ Street Address _____

City _____ State _____ ZIP Code _____ Telephone (_____) _____

Fax (_____) _____ Office Contact _____ State License # _____ National Provider ID # _____

Patient Information

Name (First, Middle Initial, Last) _____ ☐ Male ☐ Female DOB: Month/Day/Year _____ Age (years) _____

Last 4 digits of Social Security # _____ Email Address _____ Street Address _____

City _____ State _____ ZIP Code _____

Home Telephone (_____) _____ Mobile Telephone (_____) _____ Work Telephone (_____) _____

Caregiver Name (First, Last) _____ Relationship to Patient _____ Caregiver Telephone (_____) _____

Insurance Information

Please attach copies of both sides of patient's insurance card(s) ☐ Check if patient does not have insurance

Lopressor® Prescription, Waiver, Prescribing Physician Signature, and Prescription Instructions

Prescription: Lopressor® (Metoprolol Tartrate) Oral Solution 10 mg/mL ☐ **Other:** _____

Diagnosis: The ICD-10 codes for Hypertension are I10

☐ I10 Essential (primary) hypertension ☐ Other ICD-10 code(s): _____

Diagnosis: The ICD-10 codes for Angina Pectoris is I120.9

☐ I120.9 Angina NOS; anginal syndrome; cardiac angina; ischemic chest pain ☐ Other ICD-10 code(s): _____

Diagnosis: The ICD-10 codes for Myocardial Infarction is I121:1–I121.3

☐ I21.0ST (STEMI) myocardial infarction of anterior wall ☐ I21.1ST (STEMI) myocardial infarction of inferior wall ☐ I21.2ST (STEMI) myocardial infarction of other sites

☐ I21.3ST (STEMI) myocardial infarction of unspecified site ☐ I21.4 (NSTEMI) myocardial infarction ☐ Other ICD-10 code(s): _____

Dose: Administer _____ **mL of Lopressor® (Metoprolol Tartrate) Oral Solution per day**

Dispense: ☐ **300 mL bottle (NDC 30698-464-30)** **Refill:** _____

Special Instructions: _____

Special Precautions (eg, allergies): _____

Prescriber Signature: _____ **Date** _____
(stamps not acceptable)

☐ (HCP initials here)
DISPENSE AS WRITTEN Please handwrite any special instructions required by your state (eg, "brand medically necessary") here: _____

Prescriber Signature: _____ **Date** _____
(stamps not acceptable)

"By signing this form, I certify that therapy with Lopressor® (Metoprolol Tartrate) oral solution is medically necessary for the patient identified in this application ("Patient"). I have reviewed the current Lopressor® Prescribing Information and will be supervising Patient's treatment. I have received from Patient, or his/her personal representative, the necessary authorization to release, in accordance with applicable federal and state law regulations, referenced medical and/or other patient information relating to Lopressor® therapy to Validus Pharmaceuticals LLC including its agents or contractors (the "Company"), for the purpose of seeking information related to coverage and/or assisting in initiating or continuing Lopressor® therapy. I authorize Validus Patient Support Program to transmit this prescription to a pharmacy within the Lopressor® pharmacy network. I agree that product provided shall only be used for Patient and understand that I am under no obligation to prescribe or purchase Lopressor® or any other product manufactured by the Company. I certify I have received nothing of value from the Company or its agents or representatives for prescribing a Company product."

Patient Name: _____ **Date of Birth:** _____

Patient Authorization to Share Personal Health Information and Validus Liquid Innovation with Care Patient Support Enrollment. Please Read Through the Language Before Signing the Authorization and Consent

I authorize Validus Pharmaceuticals LLC ("Validus") to use this information to assess my eligibility for participation in the Patient Assistance Program ("Program"), including the audit of my medical records and/or by contacting my health care provider, my insurance company and/or me directly to confirm my eligibility or receipt of the requested medication ("Program Drug") or matters related to the Program. I understand that this assistance is temporary and that the Program may be discontinued or changed at any time. I understand that Validus will use my personal information in connection with the operation of the Program and issues related to the Program. I certify that I am a U.S. resident, do not have the ability to pay for Program Drug, earn less than 200% of the current Federal Poverty Level, and have no government or private insurance to pay for Program Drug. I certify that I do not have other sufficient financial resources or assets to pay for Program Drug or that paying for Program Drug from my own resources or assets would cause me severe financial hardship. I understand that I am expected to seek any available government assistance before applying or reapplying to the Program. I agree to notify Validus if my insurance coverage or financial situation changes. I agree not to submit an insurance claim or any other claim for payment to any third party payor (private or government) for Program Drug. I understand and agree that, if I am a Medicare Part D enrollee, I will not apply or claim any Program Drug towards True-Out of Pocket (TROOP) costs. If I am enrolled in a Medicare Part D Plan, the Program will not deny my re-application during a Medicare Part D plan year based on a change relating to availability of Medicare Part D coverage (except LIS eligibility). I agree not to resell, offer for sale, trade or barter any Program Drug and certify that it will be utilized solely for my personal use. I understand that Program Drug may not be returned for credit. I understand that I will be deemed ineligible to participate in the Program if I provide any incorrect or false information to Validus or violate any of the terms of the Program. I have read, understood and agree to all terms of this Patient Declaration. I attest the foregoing is true and that the information provided in this Enrollment Application is accurate, correct and complete.

I understand that I may refuse to sign this Authorization and that refusing to sign this Authorization will not change the way my physician, health insurance, and pharmacy providers treat me. I also understand that if I do not sign this Authorization, I will not be able to participate.

Patient Printed Name: _____ **Date:** _____

☐ Patient HIPAA form on file

Patient/ Guardian/ Physician Signature if HIPPA form on file: _____ **Date:** _____

Validus Liquid Innovation with Care Patient Support Enrollment (must check box below to be enrolled in product support services through Validus Liquid Innovation with Care Patient Support)

☐ By checking this box, I am electing to enroll in the Services and direct all disclosures of my Information in connection with such Services (which may include, but is not limited to, verification of insurance benefits and drug coverage, prior authorization support, financial assistance with co-pays, patient assistance programs, alternate funding sources, other related programs, communication with me or my prescribing physician by mail, email, or telephone about my medical condition, treatment, care management, product information and health insurance).

Consent for Marketing Communications

☐ By checking this box, I authorize the use of my Information for Validus marketing activities and consent to receiving marketing and promotional communications from Validus. I hereby give consent to Validus, its affiliates, and their agents and representatives to send communications and information to me via the contact information I have provided above. I understand that this consent will be in effect until I cancel such authorization.

Please see Important Safety Information on page 2 and full Prescribing Information provided by a Validus representative or at https://liquid.lopressor.us.com/

A patient signature is required for patient authorization to share personal health information and Validus Liquid Innovation with Care Patient Support Enrollment.

IMPORTANT SAFETY INFORMATION

INDICATIONS AND USAGE

LOPRESSOR is a beta-adrenergic blocker indicated in adult patients:

• For the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and non-fatal cardiovascular events, primarily strokes and myocardial infarctions.

• In the long-term treatment of angina pectoris.

• In the treatment of hemodynamically stable patients with definite or suspected myocardial infarction, to reduce the risk of cardiovascular mortality when used in conjunction with intravenous metoprolol therapy

CONTRAINDICATIONS

LOPRESSOR is contraindicated in severe bradycardia, second- or third-degree heart block, cardiogenic shock, systolic blood pressure <100, decompensated heart failure, sick sinus syndrome (unless a permanent pacemaker is in place), and in patients who are hypersensitive to any component of this product.

WARNINGS AND PRECAUTIONS

Abrupt Cessation of Therapy

Abrupt cessation of LOPRESSOR can cause exacerbations of angina pectoris and in some cases, myocardial infarction. Taper the dose over a period of 1–2 weeks and monitor closely particularly in patients with ischemic heart disease. If angina markedly worsens or acute coronary ischemia develops, promptly reinstate LOPRESSOR, and take measures appropriate for the management of unstable angina. Warn patients not to interrupt therapy without their physician's advice. Because coronary artery disease is common and may be unrecognized, avoid abruptly discontinuing LOPRESSOR in patients treated only for hypertension. .

Heart Failure

LOPRESSOR may temporarily worsen cardiac failure during up-titration. If such symptoms occur, increase diuretics and restore clinical stability before advancing the dose of LOPRESSOR. Dose reduction or temporary discontinuation may be needed, but such episodes do not preclude subsequent successful titration of LOPRESSOR.

Bronchospastic Disease

Patients with bronchospastic disease, in general, should not receive beta-blockers, including LOPRESSOR. Because of its relative $beta_1$ cardio-selectivity, however, LOPRESSOR may be used in patients with bronchospastic disease who do not respond to, or cannot tolerate, other antihypertensive treatment.

Pheochromocytoma

If LOPRESSOR is used in the setting of pheochromocytoma, it should be given in combination with an alpha blocker, and only after the alpha blocker has been initiated

Major Surgery

Avoid initiation of a high-dose regimen of beta-blocker therapy in patients undergoing non-cardiac surgery, since such use in patients with cardiovascular risk factors has been associated with bradycardia, hypotension, stroke and death. Chronically administered beta-blocking therapy should not be routinely withdrawn prior to major surgery, however, the impaired ability of the heart to respond to reflex adrenergic stimuli may increase the risks of general anesthesia and surgical procedures.

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 or children and patients who are fasting (i.e., surgery, not eating regularly, or are vomiting). If severe hypoglycemia occurs, patients should be instructed to seek emergency treatment.

Thyrotoxicosis

Beta adrenergic blockade may mask certain clinical signs of hyperthyroidism, such as tachycardia. Abrupt withdrawal of beta-blockade may precipitate a thyroid storm.

Risk of Anaphylactic Reaction

While taking beta-blockers, patients with a history of severe anaphylactic reaction to a variety of allergens may be more reactive to repeated challenge, either accidental, diagnostic, or therapeutic. Such patients may be unresponsive to the usual doses of epinephrine used to treat allergic reactions.

Peripheral Vascular Disease

Lopressor can precipitate or aggravate symptoms of arterial insufficiency in patients with peripheral vascular disease.

See Full Prescribing Information for additional warnings and precautions associated with LOPRESSOR.

LOP-003-25

ADVERSE REACTIONS

The following adverse reactions are described elsewhere in the labeling:

- Worsening angina or myocardial infarction
- worsening heart failure
- worsening AV block

See Full Prescribing Information for additional adverse reactions associated with LOPRESSOR

DRUG INTERACTIONS

Catecholamine Depleting Drugs

Catecholamine depleting drugs (e.g., reserpine, MAO inhibitors) can increase the risk of bradycardia or hypotension, which may produce vertigo, syncope, or postural hypotension.

Epinephrine

While taking beta-blockers, patients with a history of severe anaphylactic reactions to various allergens may exhibit increased sensitivity to repeated exposure and may not respond adequately to usual doses of epinephrine used for treating allergic reactions.

CYP2D6 Inhibitors

Strong CYP2D6 inhibitors—such as quinidine, fluoxetine, paroxetine, and propafenone—have been shown to double plasma concentrations of metoprolol. Although data on moderate or weak inhibitors are lacking, they may also elevate metoprolol levels. Increased plasma concentrations can reduce the cardioselectivity of metoprolol. If co-administration is unavoidable, patients should be monitored closely.

Negative Chronotropes

Digitalis glycosides, clonidine, diltiazem, and verapamil reduce the heart rate by slowing atrioventricular conduction. When used with beta-blockers, the risk of bradycardia may increase *See Full Prescribing Information for additional potential drug interactions associated with LOPRESSOR.*

USE IN SPECIFIC POPULATIONS

Pregnancy

If high blood pressure or a heart attack is not treated during pregnancy, it can be harmful to both the mother and baby. Metoprolol can pass through the placenta, so babies born to mothers taking this medication may be at risk for low blood pressure, low blood sugar, a slow heart rate, and trouble breathing. Babies should be closely monitored after birth if the mother took metoprolol during pregnancy.

Lactation

No adverse reactions of metoprolol on the breastfed infant have been identified. There is no information regarding the effects of metoprolol on milk production.

Females and males of reproductive potential

Based on the published literature, metoprolol may cause erectile dysfunction and inhibit sperm motility.

Pediatric Use

Pediatric use of LOPRESSOR has not been studied.

Geriatric Use

In general, use a low initial starting dose in elderly patients given their greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Hepatic Impairment

LOPRESSOR has not been studied in patients with hepatic impairment.

Renal Impairment

The systemic availability and half-life of metoprolol in patients with renal failure do not differ to a clinically significant degree from those in normal subjects. No reduction in dosage is needed in patients with chronic renal failure.

OVERDOSAGE

Overdosage of LOPRESSOR may lead to severe bradycardia, hypotension, and cardiogenic shock. Clinical presentation can also include atrioventricular block, heart failure, bronchospasm, hypoxia, impairment of consciousness/coma, nausea and vomiting.

LOPRESSOR is available as a 10 mg/mL oral solution.

To report SUSPECTED ADVERSE REACTIONS, contact Validus Pharmaceuticals LLC at 1-866-982-5438 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Full Prescribing Information at https://liquid.lopressor.us.com/

Validus PHARMACEUTICALS LLC