

\*For eligible patients. Eligibility criteria and Terms and Conditions apply. Third party trademarks used herein are trademarks of their respective owners. <u>See page 4 for full Eligibility Criteria and Terms & Conditions.</u>

Please see **Important Safety Information**, including Boxed WARNINGS, on page 3.

CAPLYTA (lumateperone) capsules



Once a clinical decision has been made to prescribe CAPLYTA, introducing CAPLYTA with Men

# Our patient support program services can help your eligible\* patients start and stay on therapy

From first prescription to ongoing therapy, our comprehensive program services are designed to make treatment access simple, affordable, and seamless. With savings options, trial vouchers, and streamlined prior authorization support, you can feel confident knowing your eligible\* patients have the help they need—every step of the way.



## **Prescription Savings**

Eligible\* patients may be able to:

- Pay as little as \$0 for the first 2 fills of CAPLYTA, up to a 30-day supply
- For fills 3 and beyond, pay as little as \$0 for a 30-, 60-, or 90-day supply
- Pay as little as \$0 for a generic antidepressant

Eligible\* patients can text "CAPLYTA" to 26789 for a downloadable digital savings card and ongoing support.



### Free Voucher\*

This 15- or 30-day trial offer helps you and your patients start immediately and determine if CAPLYTA is right for them.

Offer is valid whether patients are enrolled in commercial insurance plans, participating in Medicare, Medicaid, and other federal and state healthcare programs, or uninsured.



#### Streamlined Prior Authorization Access

**CoverMyMeds®** helps you and your office staff with the Prior Authorization process, including:

- Support for submitting requests to any healthcare plan
- Faster determinations, often in real time
- Appeals for denied requests
- Call 866-452-5017 for more information



**8 out of 10 patients paid no more than \$20** for their 30- or 90-day prescription of CAPLYTA

### Three ways eligible† patients can get a CAPLYTA Savings Card



Patients can receive a **Savings Card via text** and sign up for savings and refill reminders. **Text CAPLYTA to 26789**.



Patients can download the Savings Card at CAPLYTA.com



Provide your **eligible**<sup>†</sup> **patients** with the CAPLYTA Savings Card

\*For eligible patients. Eligibility criteria and Terms and Conditions apply. Third party trademarks used herein are trademarks of their respective owners. Eligible† patients can text "CAPLYTA" to 26789 to receive on their phone. Message and data rates may apply. Message frequency varies. Text HELP for help. Text STOP to end. See Terms and Conditions at engagedrx.com/cap and Privacy Policy at intracellulartherapies.com/privacy-policy.

<sup>†</sup>This offer is valid for eligible new or existing patients who are filling a prescription for CAPLYTA. Eligible patients must be 18 years of age or older, residents of the U.S., excluding Puerto Rico, and have a valid prescription for CAPLYTA for a Food & Drug Administration approved indication. This Savings program is valid ONLY for patients with private commercial insurance and NOT valid for prescriptions reimbursed under Medicaid, a Medicare drug benefit plan, TRICARE, or other federal or state health programs. Offer is only good at participating retail pharmacies. Offer is not transferable, is not insurance, has no cash value, and may not be used in combination with other offers. Void if prohibited by law, taxed, or restricted.

All participants are responsible for reporting the receipt of all Program benefits as required by their insurance provider. No party may seek reimbursement for all or any of the benefits received through this Program. Johnson & Johnson reserves the right to rescind, revoke, or amend the Program without notice at any time. Additional eligibility criteria apply. See back cover for full Eligibility Criteria and Terms & Conditions.

Please see Important Safety Information, including Boxed WARNINGS, on page 3.



#### **INDICATIONS**

CAPLYTA is indicated in adults for adjunctive therapy along with antidepressants for the treatment of major depressive disorder (MDD); the treatment of depressive episodes associated with bipolar I or II disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate; and the treatment of schizophrenia.

#### **IMPORTANT SAFETY INFORMATION**

#### **BOXED WARNINGS:**

- Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. CAPLYTA is not approved for the treatment of patients with dementia-related psychosis.
- Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors. The safety and effectiveness of CAPLYTA have not been established in pediatric patients.

**CONTRAINDICATIONS:** CAPLYTA is contraindicated in patients with a history of hypersensitivity to lumateperone or any components of CAPLYTA. Reactions have included pruritus, rash (e.g., allergic dermatitis, papular rash, and generalized rash), and urticaria.

**WARNINGS & PRECAUTIONS:** Antipsychotic drugs have been reported to cause:

- Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis, including stroke and transient ischemic attack. See Boxed WARNING above.
- Neuroleptic Malignant Syndrome, which is a potentially fatal reaction. Signs and symptoms include hyperpyrexia, muscle rigidity, delirium, autonomic instability, elevated creatinine phosphokinase, myoglobinuria (and/or rhabdomyolysis), and acute renal failure. Manage with immediate discontinuation of CAPLYTA and provide intensive symptomatic treatment and monitoring.
- Tardive Dyskinesia (TD) may develop in patients treated with antipsychotic drugs, including CAPLYTA. TD can develop after a relatively brief treatment period, even at low doses, or after treatment discontinuation. The TD risk appears to be highest in elderly women. The likelihood that TD will become irreversible increases with the duration of the antipsychotic drug treatment and cumulative dose. If signs and symptoms of TD appear, consider discontinuing CAPLYTA if clinically appropriate.
- Metabolic Changes, including hyperglycemia, diabetes mellitus, dyslipidemia, and weight gain. Hyperglycemia, in some cases extreme and associated with ketoacidosis, hyperosmolar coma or death, has been reported in patients treated with antipsychotics. Measure weight and assess fasting plasma glucose and lipids when initiating CAPLYTA and monitor periodically during long-term treatment.
- Leukopenia, Neutropenia, and Agranulocytosis (including fatal cases). Perform complete blood counts in patients with pre-existing low white blood cell count (WBC) or history of leukopenia or neutropenia. Consider discontinuing CAPLYTA if clinically significant decline in WBC occurs in absence of other causative factors. Discontinue CAPLYTA in patients with clinically significant neutropenia or absolute neutrophil count <1000/mm³ and monitor closely until neutropenia resolves.
- Orthostatic Hypotension and Syncope. Monitor heart rate and blood pressure and warn patients with known cardiovascular or cerebrovascular disease. Orthostatic vital signs should be monitored in patients who are vulnerable to hypotension.

- Falls. CAPLYTA may cause somnolence, postural hypotension, and motor and/or sensory instability, which may lead to falls and, consequently, fractures and other injuries. Assess patients for fall risk when initiating treatment and periodically during long-term treatment.
- Seizures. Use CAPLYTA cautiously in patients with a history of seizures or with conditions that lower seizure threshold.
- Potential for Cognitive and Motor Impairment. Advise patients to use caution when operating machinery or motor vehicles until they know how CAPLYTA affects them.
- Body Temperature Dysregulation. Use CAPLYTA with caution in patients who may experience conditions that may increase core body temperature such as strenuous exercise, extreme heat, dehydration, or concomitant anticholinergics.
- Dysphagia. Use CAPLYTA with caution in patients at risk for aspiration.

#### **DRUG INTERACTIONS:**

- Avoid concomitant use with CYP3A4 inducers.
- Reduce dose for concomitant use with strong CYP3A4 inhibitors (10.5 mg) or moderate CYP3A4 inhibitors (21 mg).
- Increased monitoring for serotonin reuptake inhibitor (SRI)-associated adverse reactions is recommended when used with SRIs; including in geriatric patients who may be at greater risk for clinically significant hyponatremia.

**SPECIAL POPULATIONS:** Neonates exposed to antipsychotic drugs during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. Reduce dose for patients with moderate (Child-Pugh class B) or severe (Child-Pugh class C) hepatic impairment (21 mg).

**ADVERSE REACTIONS:** The most common adverse reactions in clinical trials (≥5% and greater than twice placebo) with CAPLYTA vs placebo were:

- Major Depressive Disorder (Adjunctive therapy): dizziness (17% vs 5%), dry mouth (13% vs 3%), somnolence/sedation (12% vs 2%), nausea (9% vs 4%), fatigue (8% vs 2%) and diarrhea (5% vs 1%).
- Bipolar Depression (Monotherapy, Adjunctive therapy): somnolence/sedation (13% vs 3%, 13% vs 3%), dizziness (8% vs 4%, 11% vs 2%), nausea (8% vs 3%, 9% vs 4%), and dry mouth (5% vs 1%, 5% vs 1%).
- Schizophrenia: somnolence/sedation (24% vs 10%) and dry mouth (6% vs 2%).

CAPLYTA is available in 42 mg, 21 mg, and 10.5 mg capsules. US-CAP-2500828

## SAVINGS PROGRAM ELIGIBILITY CRITERIA AND FULL TERMS & CONDITIONS

\*By using the CAPLYTA Savings Card, you acknowledge that you currently meet all Eligibility Criteria and Terms & Conditions and will comply with the terms & conditions below.

#### PROGRAM ELIGIBILITY CRITERIA AND TERMS & CONDITIONS:

This offer is valid for eligible new or existing patients who are filling a prescription for CAPLYTA.

Patients must be 18 years of age or older, residents of the United States, excluding Puerto Rico, and have a valid prescription for CAPLYTA.

Patients must have private commercial insurance. Offer is <u>not</u> valid for prescriptions reimbursed under Medicaid, a Medicare drug benefit plan, TRICARE, or other federal or state health programs (such as medical assistance programs). This offer is not insurance, has no cash value and may not be used in combination with any other discount, coupon, rebate, free trial, savings, or similar offer.

This savings card is not valid when the entire cost of your prescription drug is eligible to be reimbursed by your private insurance plan or other private health or pharmacy benefit programs. You must deduct the value of this savings card from any reimbursement request submitted to your private insurance plan, either directly by you or on your behalf. You are responsible for reporting use of the savings card to any private commercial insurer, health plan, or other third party who pays for or reimburses any part of the prescription filled using the savings card, as may be required. You should not use the savings card if your insurer or health plan prohibits use of manufacturer savings cards.

This offer is good only at participating retail pharmacies. This card may not be redeemed for cash. Void if prohibited by law, taxed, or restricted. Eligible patients may pay as little as \$0 on the first two fills, up to the maximum lifetime benefit based on current list price of 30-day supply. On subsequent uses, eligible patients may pay as little as \$0, up to the maximum benefit of \$700 for a 30-day Rx; \$1,400 for a 60-day Rx; and \$2,100 for a 90-day Rx. Eligible, commercially insured patients who are taking CAPLYTA as an adjunctive or add-on treatment for Major Depressive Disorder may pay as little as \$0 per prescription fill for a generic antidepressant with a maximum benefit of \$100 per fill.

Program benefit calculated on FDA-approved dosing.

A valid Prescriber ID# is required on the prescription. Johnson & Johnson reserves the right to rescind, revoke, or amend this offer without notice at any time.

Data related to the redemption of this savings card may be collected, analyzed, and shared with Johnson & Johnson for market research and/or other purposes related to assessing the CAPLYTA Savings Program.

By using this offer, you authorize the CAPLYTA Savings Program to share your prescription information with CoverMyMeds so that CoverMyMeds may contact your healthcare provider to request submission of information to support coverage of your CAPLYTA

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prescription by your health insurance plan.

This program is valid through 09/30/2026.

No other purchase is necessary.

Johnson & Johnson reserves the right to rescind, revoke, or amend this offer without notice.

Patients with questions about the CAPLYTA Savings Card should call 1-800-639-4047.

Pharmacist: When you apply this offer, you are certifying that you have not submitted a claim for reimbursement under any federal, state, or other governmental programs for this prescription. This offer is valid only for patients with commercial insurance. Participation in this program must comply with all applicable laws and regulations as a pharmacy provider. By participating in this program, you are certifying that you will comply with the terms & conditions described in the Restrictions section below.

Pharmacist instructions for a patient with an Eligible Third Party: Submit the claim to the primary Third-Party Payer first, then submit the balance due to **Change Healthcare** as a Secondary Payer as a copay-only billing using a valid Other Coverage Code. Eligible patients may pay as little as \$0 on the first two uses, up to the maximum lifetime benefit based on current list price of 30-day supply. On subsequent uses, eligible patients may pay as little as \$0 up to the maximum benefit of \$700 for a 30-day Rx; \$1,400 for a 60-day Rx; and \$2,100 for a 90-day Rx. Eligible, commercially insured patients who are taking CAPLYTA as an adjunctive or add-on treatment for Major Depressive Disorder may pay as little as \$0 per prescription fill for a generic antidepressant with a maximum benefit of \$100 per fill. Reimbursement will be received from **Change Healthcare**.

For any questions regarding **Change Healthcare** online processing, please call the Help Desk at 1-800-433-4893.

Restrictions: This offer is valid in the United States, excluding Puerto Rico. Offer not valid for prescriptions reimbursed under Medicaid, a Medicare drug benefit plan, TRICARE, or other federal or state health programs (such as medical assistance programs). This offer is valid only for patients with commercial insurance. Cash Discount Cards and other non-insurance plans are not valid as primary under this offer. If the patient is eligible for drug benefits under any such program, the patient cannot use this offer. By using this offer, the patient certifies that he or she will comply with any terms of his or her health insurance contract requiring notification to his or her payer of the existence and/or value of this offer. It is illegal to (or offer to) sell, purchase, or trade this offer. Program expires 09/30/2026. This offer is not transferable and is limited to one offer per person. Not valid if reproduced.

Void where prohibited by law. Program managed by ConnectiveRx on behalf of Johnson & Johnson.

Johnson & Johnson reserves the right to rescind, revoke, or amend this offer without notice at any time.

