#### FOR SCHIZOPHRENIA IN ADULTS



# Don't let schizophrenia hold you back

# A GUIDE FOR PATIENTS AND CAREGIVERS

CAPLYTA is a prescription medicine used to treat adults with schizophrenia.

# **Important Safety Information**

Medicines like CAPLYTA can raise the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). CAPLYTA is not approved for treating people with dementia-related psychosis.

Do not take CAPLYTA if you are allergic to any of its ingredients. Get emergency medical help if you are having an allergic reaction (e.g., rash, itching, hives, swelling of the tongue, lip, face, or throat).

Please see additional Important Safety Information on pages 12 and 13.



# WHAT IS SCHIZOPHRENIA?

Schizophrenia is a complex mental illness that can affect the way someone thinks and interacts with the world, but symptoms can be reduced with proper treatment and support. As a chronic condition, it requires life-long medication to control symptoms. Schizophrenia can also interfere with the ability to have healthy relationships, which can affect family and social life, including the ability to go to school or work.

If you or someone you love suffers from schizophrenia, you are not alone. Approximately 2.4 million people in the United States are living with schizophrenia. Schizophrenia typically starts in early adulthood. It's thought to run in families.





Schizophrenia is a complicated disease that can affect different people in different ways. Although the physical cause of schizophrenia is unknown, it is believed that imbalances between chemicals in the brain are the cause. These chemicals, known as "neurotransmitters," are dopamine, serotonin, and glutamate. Schizophrenia can result from abnormal interactions between these neurotransmitters.

Although schizophrenia may seem scary or overwhelming at times, it is important to remember that there are many things you can do to reduce the impact of schizophrenia on you or your loved ones. Talking to your healthcare provider is the first step: the more you share with them, the more they can help you.

Millions of people live and work with schizophrenia; real progress is possible. The following pages are intended to help you have more productive conversations with your healthcare provider, so each appointment feels like a positive step forward.

# COMMON SYMPTOMS OF SCHIZOPHRENIA INCLUDE:

Lack of judgement and insight	Being less able to process what's going on	
Active social avoidance	Going out of the way not to speak or interact with others	
Delusions	Unusual thoughts or beliefs	
Hallucinations	Hearing, seeing, smelling, or feeling things that aren't there	
Paranoia	Thinking unseen forces are trying to harm you	
Lack of spontaneity/conversation flow	Trouble carrying on a conversation	
Emotional withdrawal	Not being able to show or share your feelings	
Loss of pleasure	Not wanting to do things you normally would	
Flat affect	Speaking in a monotone voice with no emotion	
Inability to focus	Unable to concentrate on ordinary tasks	
Depression	Feelings of sadness, emptiness, and isolation	

Talking to a healthcare provider is the first step: the more you share with them, the more they can help you. If you or a loved one have experienced any of the symptoms above, talk to your healthcare provider as soon as you can. They can help create a treatment plan to manage you or your loved one's symptoms. Your healthcare provider will also determine whether your symptoms are frequent or severe enough to warrant a schizophrenia diagnosis.



# MOVING FORWARD AFTER A SCHIZOPHRENIA DIAGNOSIS

Once you or someone you know receives a diagnosis of schizophrenia, one or more medications will likely be prescribed by a healthcare provider. These medications can help control the symptoms of schizophrenia, although not everyone responds to a medication the same way. You may have side effects from some medications, so your healthcare provider may have you try several different medications before finding the one that works best.

Finding the right medication is important, and following your healthcare provider's instructions can help you manage your schizophrenia.



It can be difficult to tell a healthcare provider or caregiver exactly how you are feeling, but it is important that you are as honest as you can be with them. **There are many schizophrenia medications, so if a side effect is bothering you, tell your healthcare provider. They may want to change your medication.** 



# LEARN ABOUT CAPLYTA

#### What is CAPLYTA?

CAPLYTA is an FDA-approved prescription medication for adults with schizophrenia.

# **How CAPLYTA Can Help**

In 2 clinical trials, CAPLYTA was proven to help control symptoms of schizophrenia with demonstrated safety.

In both clinical trials, CAPLYTA was significantly better than a sugar pill (placebo) at managing schizophrenia symptoms. People taking CAPLYTA also showed an improvement in the overall severity of their condition, which was measured by a schizophrenia rating scale.

### **How CAPLYTA Works**

Schizophrenia is complicated. Although the exact way CAPLYTA works is unknown, it is thought to affect different brain-signaling chemicals to help control schizophrenia symptoms.

## **How to Take CAPLYTA**

CAPLYTA is a capsule, taken just once a day, with or without food. Dose titration is not required. It is important



Once-daily pill

to take it exactly as your healthcare provider has prescribed. Keep in mind that it may take a few weeks to work with your body. Talk to your healthcare provider about all the medicines you're taking, since there are some risks for drug interactions.

# **CAPLYTA** may cause serious side effects, including:

- Stroke (cerebrovascular problems) in elderly people with dementia-related psychosis that can lead to death.
- Neuroleptic malignant syndrome (NMS): high fever, confusion, changes in your breathing, heart rate, and blood pressure, stiff muscles, and increased sweating; these may be symptoms of a rare but potentially fatal condition. Contact your healthcare provider or go to the emergency room if you experience signs and symptoms of NMS.



Please see additional <u>Important Safety Information</u>, including Boxed Warnings, on pages 12 and 13.

# WHAT TO EXPECT WITH CAPLYTA

he most common side effects with CAPLYTA are sleepiness and dry mouth. Your healthcare provider may tell you what time of day or night is best for you to take CAPLYTA. Follow your healthcare provider's direction on when and how to take CAPLYTA.

# Do blood glucose, cholesterol, or triglycerides go up when on CAPLYTA?

In clinical trials, changes in blood glucose, cholesterol, and triglycerides in patients taking CAPLYTA were similar to those in patients taking a sugar pill.

# Will your weight change on CAPLYTA?

In a long-term study, patients on CAPLYTA for 1 year saw an average weight loss of 7 pounds.

CAPLYTA, like other drugs used to treat schizophrenia, may cause problems with



Each drug has its own specific risk profile.

Your healthcare provider should check your blood sugar, fat levels and weight before you start and during your treatment with CAPLYTA. Extremely high blood sugar levels can lead to coma or death. Tell your healthcare provider if you have symptoms of high blood sugar, which include feeling very thirsty, hungry, sick to your stomach, weak/tired or needing to urinate more than usual.



# Will taking CAPLYTA have an effect on hormones that affect sexual characteristics?

Patients taking CAPLYTA in clinical trials did not see an increase in prolactin (a hormone that, when levels are elevated, can cause sexual side effects including enlarged breasts, lactation, erectile dysfunction, reduced sex drive, and missed periods).

# Do patients on CAPLYTA experience movement disorders?

In clinical trials, movement disorders were uncommon and similar to a sugar pill, with 6.7% of patients taking CAPLYTA experiencing movement disorders vs 6.3% of patients taking a sugar pill.

Like other antipsychotic drugs, CAPLYTA may cause movements that you cannot control in your face, tongue, or other body parts. This can be a sign of tardive dyskinesia. Tardive dyskinesia is a movement disorder that may not go away, even if you stop taking CAPLYTA. Tardive dyskinesia may also start after you

stop taking CAPLYTA.



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# CAPLYTA may cause serious side effects, including:

- Stroke (cerebrovascular problems) in elderly people with dementia-related psychosis that can lead to death.
- Neuroleptic malignant syndrome (NMS): high fever, confusion, changes in your breathing, heart rate, and blood pressure, stiff muscles, and increased sweating; these may be symptoms of a rare but potentially fatal condition. Contact your healthcare provider or go to the emergency room if you experience signs and symptoms of NMS.
- Uncontrolled body movements (tardive dyskinesia, TD)
  in your face, tongue, or other body parts. TD may not go away,
  even if you stop taking CAPLYTA. It may also occur after you stop
  taking CAPLYTA.
- Problems with your metabolism including high blood sugar, diabetes, increased fat (cholesterol and triglyceride) levels in your blood and weight gain. Your healthcare provider should check your blood sugar, fat levels and weight before you start and during your treatment with CAPLYTA. Extremely high blood sugar levels can lead to coma or death. Call your healthcare provider if you have any of the following symptoms of high blood sugar: feeling very thirsty, hungry, sick to your stomach, needing to urinate more than usual, weak/tired, or confused, or your breath smells fruity.
- Low white blood cell count. Your healthcare provider may do blood tests during the first few months of treatment with CAPLYTA.
- Decreased blood pressure (orthostatic hypotension). You may feel lightheaded, dizzy, or faint when you rise too quickly from a sitting or lying position.
- Falls. CAPLYTA may make you sleepy or dizzy, may cause a
  decrease in your blood pressure when changing position
  (orthostatic hypotension), and can slow your thinking and
  motor skills which may lead to falls that can cause broken bones
  or other injuries.
- Seizures (convulsions).
- Sleepiness, drowsiness, feeling tired, difficulty thinking and doing normal activities. Until you know how CAPLYTA affects you, do not drive, operate heavy machinery, or do other dangerous activities.

- Problems controlling your body temperature so that you feel too warm. Avoid getting overheated or dehydrated while taking CAPLYTA.
- Difficulty swallowing that can cause food or liquid to get into the lungs.

The most common side effects of CAPLYTA include sleepiness and dry mouth.

These are not all the possible side effects of CAPLYTA. Tell your healthcare provider if you have or have had heart problems or a stroke, high or low blood pressure, diabetes, or high blood sugar,

problems with cholesterol, have or have had seizures (convulsions), kidney or liver problems, or a low white blood cell count. CAPLYTA may cause fertility problems in females and males. You should notify your healthcare provider if you become pregnant or intend to become pregnant while taking CAPLYTA. CAPLYTA may cause abnormal involuntary movements and/or withdrawal symptoms in newborn babies exposed to CAPLYTA during the third trimester. Talk to your healthcare provider if you breastfeed or are planning to breastfeed as CAPLYTA passes into breast milk. Tell your healthcare



provider about all the medicines you're taking. CAPLYTA may affect the way other medicines work, and other medicines may affect how CAPLYTA works, causing possible serious side effects. Do not start or stop any medicines while taking CAPLYTA without talking to your healthcare provider. You are encouraged to report negative side effects of prescription drugs. Contact Intra-Cellular Therapies, Inc. at 1-888-611-4824 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

CAPLYTA is available in 10.5 mg, 21 mg, and 42 mg capsules.

Please see Medication Guide, including Boxed Warnings.



# YOUR NEXT HEALTHCARE PROVIDER VISIT

# How to get the most out of your next healthcare provider's appointment

Your healthcare provider's appointments are great times to let them know about how things are going with your medication and your life. They're also great times to ask questions about things



that you are curious or concerned about. It helps to mention how well your symptoms are being controlled or if you are having trouble with side effects.

Here are some additional questions you may find helpful to ask your healthcare provider:

- Can CAPLYTA help with my schizophrenia symptoms?
- How quickly will CAPLYTA start working?
- What are the side effects for CAPLYTA and are they different from other schizophrenia medications?
- Do I need to take CAPLYTA with food?
- Will CAPLYTA make me gain weight?
- Can I take other medications with CAPLYTA?
- Will I feel any differently while on CAPLYTA?
- Do you think CAPLYTA would be right for me?

If you're still struggling, talk to your healthcare provider about the possibility of progress with CAPLYTA and visit caplyta.com/schizophrenia

# Things to talk to my healthcare provider about:

It's also OK if you forget to ask something during the appointment. One tip is to keep a little notepad with you or at home to use whenever you think of anything that you want to ask. Then, you can bring it up at your next appointment or call your healthcare provider about it.

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# **SAVINGS OFFER**

Learn how to get your savings card

PAY AS LITTLE AS

SOLUTION

FOR THE FIRST
TWO FILLS
Up to a 30-day supply

\$15 FOR SUBSEQUENT FILLS OF CAPLYTA
Up to a 90-day supply

Access your CAPLYTA Savings Card via text or scan the QR code to download it from our website.

### 1. TEXT "CAPLYTA" TO 26789

to download a digital CAPLYTA Savings Card to your phone and receive useful text messages about your prescription.

- Alerts on prescription savings
- Updates on insurance coverage
- Refill reminders and the option to order refills via text

Message and data rates may apply. Message frequency varies. Text HELP for help. Text STOP to end. See <u>Terms and Conditions</u> and <u>Privacy Policy</u>.

### 2. DOWNLOAD THE SAVINGS CARD

Scan the QR code to download and print your Savings Card from our website. Then, simply bring it to your pharmacy, show it to the pharmacist, and start saving on your CAPLYTA prescriptions.



Please see additional <u>Important Safety Information</u>, including Boxed Warnings, on pages 12 and 13.

\*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 \$15, up to the maximum benefit of \$600. Program benefit calculated on FDA-approved dosing.

A valid Prescriber ID# is required on the prescription. Intra-Cellular Therapies 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 Intra-Cellular Therapies 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 prescription by your health insurance plan.

This program is valid through 04/30/2025.

conditions described in the Restrictions section below.

No other purchase is necessary.

Intra-Cellular Therapies 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 &

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 \$15, up to the maximum benefit of \$600. 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 04/30/2025. 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 Intra-Cellular Therapies. Intra-Cellular Therapies reserves the

right to rescind, revoke, or amend

this offer without notice at any time.



# OTHER HELPFUL RESOURCES AND SUPPORT

There are many organizations out there that can help people with schizophrenia form important connections with others.

# **NAMI (National Alliance on Mental Illness)**

NAMI is an organization dedicated to building better lives for the millions of Americans with mental illness.

Website: nami.org

# **NIMH (National Institute of Mental Health)**

The National Institute of Mental Health is the lead federal agency for research on mental disorders.

Website: nimh.nih.gov

### 988 Suicide & Crisis Lifeline

If you are ever having suicidal thoughts, or just need someone to talk to, people are on call 24/7 and ready to help. You can also chat online with a specialist.

Website: suicidepreventionlifeline.org

Telephone: 1-800-273-8255

# MHA (Mental Health America)

Mental Health America is a community-based nonprofit dedicated to addressing the needs of those living with mental illness.

Website: mhanational.org

# **US Department of Health & Human Services**

It is the mission of the US Department of Health & Human Services (HHS) to enhance and protect the health and well-being of all Americans.

Website: hhs.gov

# **AFSP (American Foundation for Suicide Prevention)**

AFSP raises awareness, funds scientific research, and provides resources and aid to those affected by suicide.

Website: afsp.org

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