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.

Please see additional Important Safety Information, including Boxed Warning, on pages 16 and 17.
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 lifelong 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.

2.4 MILLION
PEOPLE IN THE UNITED STATES ARE LIVING WITH SCHIZOPHRENIA

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 is 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 him/her, the more he/she 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

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

Talking to a healthcare provider is the first step: the more you share with him/her, the more he/she 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. He/she 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.
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 him/her. There are many schizophrenia medications, so if a side effect is bothering you, tell your healthcare provider. He/she may want to change your medication.

Antipsychotic drugs, like CAPLYTA, can cause:

- **Stroke (cerebrovascular problems)** in elderly people 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 doctor or go to the emergency room if you experience signs and symptoms of NMS.

Please see additional Important Safety Information, including Boxed Warning, on pages 16 and 17.
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 sugar pill (placebo) at managing schizophrenia symptoms. The most common side effects for patients who took CAPLYTA were sleepiness (24%) and dry mouth (6%). Sleepiness was mainly mild. 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 food. In order for you to get the full benefit of the medication, it is important 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 doctor about all the medicines you’re taking, since there are some risks for drug interactions.

Important Safety Information
CAPLYTA can cause sleepiness and trouble concentrating. Until you know how CAPLYTA affects you, do not drive, operate heavy machinery, or do other dangerous activities.

Please see additional Important Safety Information, including Boxed Warning, on pages 16 and 17.
WHAT TO EXPECT WITH CAPLYTA

The 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.

Does blood glucose, cholesterol, or triglycerides go up 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 your metabolism, including high blood sugar, diabetes, increased fat (cholesterol and triglyceride) levels in your blood, and weight gain.

Each drug has its own specific risk profile.

Your doctor 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 doctor 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 sugar pill, with 6.7% of patients taking CAPLYTA experiencing movements 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.

Please see additional Important Safety Information, including Boxed Warning, on pages 16 and 17.
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 him or her 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?

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.

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

Please see additional Important Safety Information, including Boxed Warning, on pages 16 and 17.
OTHER HELPFUL RESOURCES & 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](http://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](http://nimh.nih.gov)

**National Suicide Prevention 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](http://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: [mentalhealthamerica.net](http://mentalhealthamerica.net)

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**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](http://hhs.gov)

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**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](http://afsp.org)
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.

Tell your doctor right away if you have any of the following serious side effects:

• **Stroke (cerebrovascular problems)** in elderly people 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 doctor 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 your medication.

• **Problems with your metabolism** including high blood sugar, diabetes, increased fat (cholesterol and triglyceride) levels in your blood and weight gain. Your doctor 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 doctor 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.

• **Low white blood cell count.** Your doctor 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 and trouble concentrating:** 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**

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

These are not all of the possible side effects of CAPLYTA. You should notify your doctor if you become pregnant or intend to become pregnant while taking CAPLYTA. CAPLYTA may cause extrapyramidal (abnormal involuntary movements) and/or withdrawal symptoms in newborn babies exposed to CAPLYTA during the third trimester. When taking CAPLYTA, you should not breastfeed. Tell your doctor if you have liver problems and about all the medicines you’re taking, since there are some risks for drug interactions. Avoid eating grapefruit or drinking grapefruit juice during treatment with CAPLYTA. Grapefruit and grapefruit juice may affect the amount of CAPLYTA in your blood. You are encouraged to report negative side effects of prescription drugs.

Please see full Prescribing Information, including Boxed Warning.
LYTAlink® Learn how you might be able to save on CAPLYTA

For eligible* commercially insured patients.

With the CAPLYTA Copay Savings Card, eligible patients may pay as little as $0 for their first fill and $15 for subsequent fills of CAPLYTA.

3 Ways to get the CAPLYTA Copay Savings Card:

1. Get the copay card from your doctor.
2. Visit caplyta.com and click ‘Download.’
3. Text ‘CAPLYTA’ to 26789 to get the CAPLYTA Copay eCard right on your phone through the CAPLYTA text message program.

Message & Data Rates may apply. Message frequency varies. Terms & Conditions apply: www.engagedrx.com/CAP. Once enrolled, text HELP for help. Text STOP to end. Show your pharmacist the eCard and receive the same savings plus refill reminders.

Medicare’s Extra Help Program

Patients with low-income subsidy (LIS) can get help with prescription costs through Medicare Part D. This program is known as Extra Help.

Did you know the most you will pay with Extra Help for a brand name prescription like CAPLYTA is $8.95?

Visit www.cms.gov/Medicare/Eligibility-and-Enrollment to see if you are eligible for Extra Help.

*This offer is valid for eligible new or existing patients who are filling a prescription for CAPLYTA. Eligible patients must be at least 18 years old and less than 65 years old, residents of the United States excluding Puerto Rico, and have a valid prescription for CAPLYTA for a Food & Drug Administration–approved indication. This Copay Program is valid ONLY for patients with 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 not valid for cash paying patients and 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 benefit received through this Program. ITCI reserves the right to rescind, revoke, or amend the Program without notice at any time. Additional eligibility criteria apply. See full terms and conditions at www.caplyta.com/cost-savings.