

CAPLYTA® (lumateperone)

What are the possible side effects of CAPLYTA?

CAPLYTA may cause serious side effects, including:



Increased risk of death in elderly people with dementia-related psychosis¹

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 the treatment of people with dementia-related psychosis.



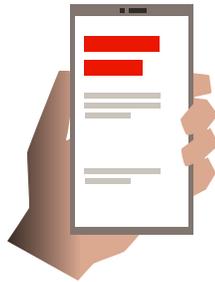
Increased risk of suicidal thoughts and actions¹

CAPLYTA and antidepressant medicines increase the risk of suicidal thoughts and actions in people 24 years of age and younger, **especially within the first few months of treatment or when the dose is changed**. Depression and other mental illnesses are the most important causes of suicidal thoughts and actions.

How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?¹



Pay close attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings. This is very important when CAPLYTA or the antidepressant medicine is started or when the dose is changed.



Call your healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings or if you develop suicidal thoughts or actions.



Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you have concerns about symptoms.

Call a healthcare provider right away if you or your family member have any of the following symptoms, especially if they are new or worse or if they worry you¹:

- Thoughts about suicide or dying
- New or worse depression
- Feeling very agitated or restless
- Trouble sleeping
- Acting aggressive, being angry, or being violent
- An extreme increase in activity and talking (mania)
- Suicide attempts
- New or worse anxiety
- Panic attacks
- New or worse irritability
- Acting on dangerous impulses
- Other unusual changes in behavior or mood

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Stroke (cerebrovascular problems) in elderly people with dementia-related psychosis that can lead to death.¹



Neuroleptic malignant syndrome¹

Neuroleptic malignant syndrome (NMS) is a serious condition that can lead to death. Call your healthcare provider or go to the nearest hospital emergency room right away if you have some or all of the following signs and symptoms of NMS:

- High fever
- Changes in your breathing, heart rate, and blood pressure
- Increased sweating
- Confusion
- Stiff muscles



Uncontrolled body movements (tardive dyskinesia)¹

CAPLYTA may cause movements that you cannot control in your face, tongue, or other body parts. Tardive dyskinesia may not go away, even if you stop taking CAPLYTA. Tardive dyskinesia may also start after you stop taking CAPLYTA.

Problems with your metabolism such as¹:



High blood sugar (hyperglycemia) and diabetes:

Increases in blood sugar can happen in some people who take CAPLYTA. Extremely high blood sugar can lead to coma or death. Your healthcare provider should check your blood sugar before you start or soon after you start CAPLYTA and then regularly during long-term treatment with CAPLYTA.

- **Call your healthcare provider if you have any of these symptoms of high blood sugar during treatment with CAPLYTA:**
 - Feel very thirsty
 - Feel very hungry
 - Feel sick to your stomach
 - Need to urinate more than usual
 - Feel weak or tired
 - Feel confused or your breath smells fruity



Increased fat levels (cholesterol and triglycerides) in your blood:

Your healthcare provider should check the fat levels in your blood before you start or soon after you start CAPLYTA, and then periodically during treatment with CAPLYTA.



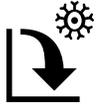
Weight gain:

You and your healthcare provider should check your weight before you start CAPLYTA and often during treatment with CAPLYTA.

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Low white blood cell count¹

Your healthcare provider may do blood tests during the first few months of treatment with CAPLYTA.



Decreased blood pressure (orthostatic hypotension)¹

You may feel lightheaded or faint when you rise too quickly from a sitting or lying position.



Falls¹

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 fractures or other injuries.



Seizures (convulsions)¹



Difficulty swallowing that can cause food or liquid to get into your lungs¹



Sleepiness, drowsiness, feeling tired, and difficulty thinking and doing normal activities¹

Do not drive, operate machinery, or do other dangerous activities until you know how CAPLYTA affects you. CAPLYTA may make you drowsy.



Problems controlling your body temperature so that you feel too warm¹

Do not become too hot or dehydrated during treatment with CAPLYTA.

- Do not exercise too much.
- In hot weather, stay inside in a cool place if possible.
- Stay out of the sun.
- Do not wear too much clothing or heavy clothing.
- Drink plenty of water.

The most common side effects of CAPLYTA include¹:

Sleepiness

Feeling tired

Dizziness

Nausea

Dry mouth

Diarrhea



CAPLYTA may cause fertility problems in females and males. Talk to your healthcare provider if this is a concern for you.¹

- These are not all the possible side effects of CAPLYTA.¹
- Call your doctor for medical advice about side effects.¹
- You may report side effects to Food and Drug Administration (FDA) at 1-800-FDA-1088.¹

This information is provided ONLY in response to your request and is not intended as medical advice, to promote the use of our product, or suggest using it in any manner other than as described in the PRESCRIBING INFORMATION. All decisions regarding your medical treatment should be made with your healthcare professional(s). Please contact your healthcare professional(s) to discuss the information in this response.

Please refer to the attached full PRESCRIBING INFORMATION and MEDICATION GUIDE for CAPLYTA.¹

1. CAPLYTA (lumateperone) [Prescribing Information]. Bedminster, NJ; Intra-Cellular Therapies, Inc.; https://www.intracellulartherapies.com/docs/caplyta_pi.pdf.