MEDICATION GUIDE

CAPLYTA (kap-LITE-ah)
(lumateperone)
capsules

What is the most important information I should know about CAPLYTA?

CAPLYTA may cause serious side effects, including:

- **Increased risk of death in elderly people with dementia related psychosis.** 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 actions.** CAPLYTA and antidepressant medicines may increase suicidal thoughts and actions in some children, adolescents, and young adults **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?

- 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, worse, or worry you:

- thoughts about suicide or dying
- new or worse depression
- feeling very agitated or restless
- trouble sleeping (insomnia)
- acting aggressive, being angry, or violent
- an extreme increase in activity and talking (mania)
- attempts to commit suicide
- new or worse anxiety
- panic attacks
- new or worse irritability
- acting on dangerous impulses
- other unusual changes in behavior or mood

What is CAPLYTA?

CAPLYTA is a prescription medicine used in adults:

- to treat schizophrenia
- alone to treat depressive episodes that happen with bipolar I or bipolar II disorder (bipolar depression)
- with the medicine lithium or valproate to treat depressive episodes that happen with bipolar I or bipolar II disorder (bipolar depression)

It is not known if CAPLYTA is safe and effective in children.

Do not take CAPLYTA if you are allergic to lumateperone or any of the ingredients in CAPLYTA. See the end of this Medication Guide for a complete list of ingredients in CAPLYTA.

Before taking CAPLYTA, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had heart problems or a stroke
- have or have had low or high blood pressure
- have or have had diabetes or high blood sugar, or a family history of diabetes or high blood sugar. Your healthcare provider should check your blood sugar before you start and during treatment with CAPLYTA.
- have or have had high levels of total cholesterol, LDL cholesterol, or triglycerides or low levels of HDL cholesterol
- have or have had seizures (convulsions)
- have or have had kidney or liver problems
- have or have had a low white blood cell count
- are pregnant or plan to become pregnant. CAPLYTA may harm your unborn baby. Taking CAPLYTA during your third trimester of pregnancy may cause your baby to have abnormal muscle movements or withdrawal symptoms after birth. Talk to your healthcare provider about the risk to your unborn baby if you take CAPLYTA during pregnancy.
  - Tell your healthcare provider if you become pregnant or think you are pregnant during treatment with CAPLYTA.
  - If you become pregnant during treatment with CAPLYTA, talk to your healthcare provider about registering with the National Pregnancy Registry for Atypical Antipsychotics. You can register by calling 1-866-961-2388 or go to http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/.
- are breastfeeding or plan to breastfeed. CAPLYTA passes into your breast milk. Talk to your healthcare provider about the risks and benefits of breastfeeding and the best way to feed your baby during treatment with CAPLYTA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

CAPLYTA and other medicines may affect each other causing possible serious side effects. CAPLYTA may affect the way other medicines work, and other medicines may affect how CAPLYTA works.

Your healthcare provider can tell you if it is safe to take CAPLYTA with your other medicines. Do not start or stop any medicines during treatment with CAPLYTA without first talking to your healthcare provider.

Know the medicines you take. Keep a list of your medicines to show your healthcare provider and pharmacist when you get a new medicine.

How should I take CAPLYTA?

- Take CAPLYTA exactly as your healthcare provider tells you to take it. Do not change the dose or stop taking CAPLYTA without first talking to your healthcare provider.
- Take CAPLYTA 1 time each day with or without food.
- If you take too much CAPLYTA, call your healthcare provider or Poison Control Center at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What should I avoid while taking CAPLYTA?

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

What are the possible side effects of CAPLYTA?

CAPLYTA may cause serious side effects, including:

- **See "What is the most important information I should know about CAPLYTA?"**
- **Stroke (cerebrovascular problems) in elderly people with dementia-related psychosis that can lead to death.**
- **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).** 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 as:**
  - **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 and often during treatment with CAPLYTA.
- **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 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 fractures or other injuries.
- **Seizures (convulsions).**
- **Sleepiness, drowsiness, feeling tired, difficulty thinking and doing normal activities.** See "What should I avoid while taking CAPLYTA?"
- **Problems controlling your body temperature so that you feel too warm.** See "What should I avoid while taking CAPLYTA?"
- **Difficulty swallowing** that can cause food or liquid to get into your lungs.

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

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

These are not all the possible side effects of CAPLYTA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store CAPLYTA?

- Store CAPLYTA at room temperature between 68°F to 77°F (20°C to 25°C).

Keep CAPLYTA and all medicines out of the reach of children.

General information about the safe and effective use of CAPLYTA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use CAPLYTA for a condition for which it was not prescribed. Do not give CAPLYTA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about CAPLYTA that is written for healthcare professionals.

What are the ingredients in CAPLYTA?

Active ingredient: lumateperone

Inactive ingredients: croscarmellose sodium, gelatin, magnesium stearate, mannitol, and talc. Colorants include FD&C blue #1 and red #3 (42 mg), FDA/E172 black iron oxide, FDA/E172 red iron oxide and FD&C red #3 (10.5 mg), and titanium dioxide (42 mg, 21 mg and 10.5 mg).

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For more information, go to www.CAPLYTA.com or call (888) 252-4824

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