



LYBALVI[®]
olanzapine and samidorphan
5 mg/10 mg · 10 mg/10 mg · 15 mg/10 mg
20 mg/10 mg tablets

Actor portrayal.

Experiencing bipolar 1 symptoms?

GET HELP TO
PUSH BACK

Indications and Important Safety Information

LYBALVI[®] is a prescription medicine that contains 2 medicines (olanzapine and samidorphan) used in adults:

- alone for short-term (acute) or maintenance treatment of manic or mixed episodes that happen with bipolar I disorder
- in combination with valproate or lithium to treat manic or mixed episodes that happen with bipolar I disorder
- to treat schizophrenia

It is not known if LYBALVI is safe or effective in children.

LYBALVI may cause serious side effects, including increased risk of death in elderly people with dementia-related psychosis. LYBALVI increases the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). LYBALVI is not approved for the treatment of people with dementia-related psychosis.

Please see additional Important Safety Information throughout and full Prescribing Information, including Boxed Warning and Medication Guide.

How can LYBALVI[®] help you PUSH BACK?



LYBALVI provides both short-term and maintenance treatment of bipolar 1 symptoms.



LYBALVI is a prescription medication taken by mouth once daily, with or without food.



Commercially insured eligible patients may pay as little as \$0 for their first 3 prescription fills of LYBALVI with the LYBALVI Co-pay Savings Program; Terms and Conditions apply.

Important Safety Information (cont'd)

Do not take LYBALVI if you are taking opioids or are experiencing acute opioid withdrawal.

LYBALVI may cause serious side effects, including:

- **Stroke (cerebrovascular problems) in elderly people with dementia-related psychosis that can lead to death.**
- **Opioid withdrawal. Do not** take LYBALVI for at least 7 days after you stopped taking short-acting opioids and for at least 14 days after you stopped taking long-acting opioids. One of the medicines in LYBALVI (samidorphan) can cause opioid withdrawal that may be severe and cause hospitalization in people who are physically dependent on opioids. Talk to your healthcare provider if you have questions about the type of opioid you take.

Actor portrayals.

A proven treatment for bipolar 1

We know there's a lot to think about when considering a treatment option. Here, you'll find information to help you learn about topics like:

- ✓ How LYBALVI may help manage your bipolar 1 symptoms
- ✓ How one of the ingredients in LYBALVI, olanzapine, helped people with bipolar 1 go longer without symptom relapse
- ✓ How to take LYBALVI
- ✓ When not to take and what to avoid while taking LYBALVI
- ✓ Details about how you may be able to save on LYBALVI with the LYBALVI Co-pay Savings Program

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Actor portrayals.

Are you living with symptoms of bipolar 1?

If you're living with bipolar 1, you might be experiencing days or weeks of manic (up) or depressive (down) symptoms. If you're feeling both up and down symptoms at the same time, you could be experiencing what's called a **mixed episode**.



MANIC EPISODES

can make you feel overly excited or irritable



DEPRESSIVE EPISODES

can leave you feeling hopeless, sad, or indifferent



MIXED EPISODES

can make you feel up and down at the same time; for example, you might be feeling very sad but also energized

How do you know if you're experiencing mixed episodes?

Having both up and down symptoms of bipolar 1 at the same time can be frustrating and confusing. It may seem like your feelings don't fit together.

Your healthcare provider can help you identify if you're having mixed episodes.

Let's talk about symptoms you may have experienced

Below are some examples of manic (up) and depressive (down) symptoms people with bipolar 1 can experience. This is not a complete list, but you can use it as a starting point to talk to your healthcare provider about symptoms you may have experienced.



SOME MANIC (UP) SYMPTOMS^a

- A sudden and abnormally high increase in self-confidence
- Racing thoughts
- Feeling like you don't need as much sleep
- Agitation
- Disruptive behavior



SOME DEPRESSIVE (DOWN) SYMPTOMS^a

- Sad or empty feelings
- Not enjoying or wanting to partake in usual interests
- Having less energy
- Feeling guilty or worthless
- Thinking more about death and suicide



MIXED EPISODES

If you have experienced **both** manic and depressive symptoms at the same time, you might be having mixed episodes.

Talk to your healthcare provider about all of your symptoms.

^aThis is a partial list of bipolar 1 symptoms people may experience. This treatment has not been shown to improve any symptom individually and is not approved to treat depressive episodes.



LYBALVI® is proven to treat manic or mixed episodes of bipolar 1

One of the medicines in LYBALVI, olanzapine, has been proven to reduce manic or mixed episodes of bipolar 1 in adults.

In a 48-week study of olanzapine, adults with manic or mixed episodes of bipolar 1 were observed for relapse.^a



Among the 361 people who did not have a relapse of symptoms while on olanzapine for at least 2 weeks prior to the start of the study, 225 continued to take olanzapine and 136 switched to placebo (sugar pill).

^aRelapse was defined as an increase in manic, depressive, or mixed episode-related symptoms on 2 standard surveys (YMRS and HAM-D), or being hospitalized for either mania or depression.

In this study, patients taking olanzapine had a significantly longer time to relapse than those taking a placebo (sugar pill).^a

In this study, the median time to relapse was 24 weeks for people taking olanzapine and 3 weeks for those taking placebo.



Important Safety Information (cont'd)

LYBALVI may cause serious side effects, including:

- **Risk of life-threatening opioid overdose.** You should not start taking opioids for at least 5 days after you stop treatment with LYBALVI. One of the medicines in LYBALVI (samidorphan) can increase your chance of having an opioid overdose that can cause death if you take opioids during treatment or within 5 days after stopping treatment with LYBALVI.

You can accidentally overdose in 2 ways:

- LYBALVI blocks the effects of opioids, such as heroin, methadone, or opioid pain medicines. **Do not** take large amounts of opioids to try to overcome the opioid-blocking effects of LYBALVI. This can lead to serious injury, coma, or death.
- After you take LYBALVI, its blocking effect slowly decreases and completely goes away over time. You may be more sensitive to the effects of opioids. If you have used opioid street drugs or opioid-containing medicines in the past, using opioids in amounts that you used before treatment with LYBALVI can lead to overdose or death.

It is important that you tell your family and the people closest to you of this increased sensitivity to opioids and the risk of overdose.

Please see additional Important Safety Information throughout and full Prescribing Information, including Boxed Warning and Medication Guide.

Before taking LYBALVI[®]

Make sure your healthcare provider knows about all of your medical conditions, including:



If you're currently pregnant, you plan to be pregnant, or if you're breastfeeding or plan to breastfeed

Also talk to them about the risks to you or your unborn or newborn baby if you take LYBALVI.



Any medicines you take or plan to take

This includes prescription and over-the-counter medicines, vitamins, and herbal supplements. Tell your healthcare provider if any of your medications contain olanzapine. Your healthcare provider can tell you what medicines are safe to take with LYBALVI, so make sure to talk to them first.



Any opioids you take

Be sure to share if you've taken or stopped taking opioids in the past 14 days, whether by prescription or not. For more details, see pages [12 & 13](#).



If you think you might have a urine drug screening test

LYBALVI could affect these results. Make sure you tell the person who is administering the test that you're taking LYBALVI.

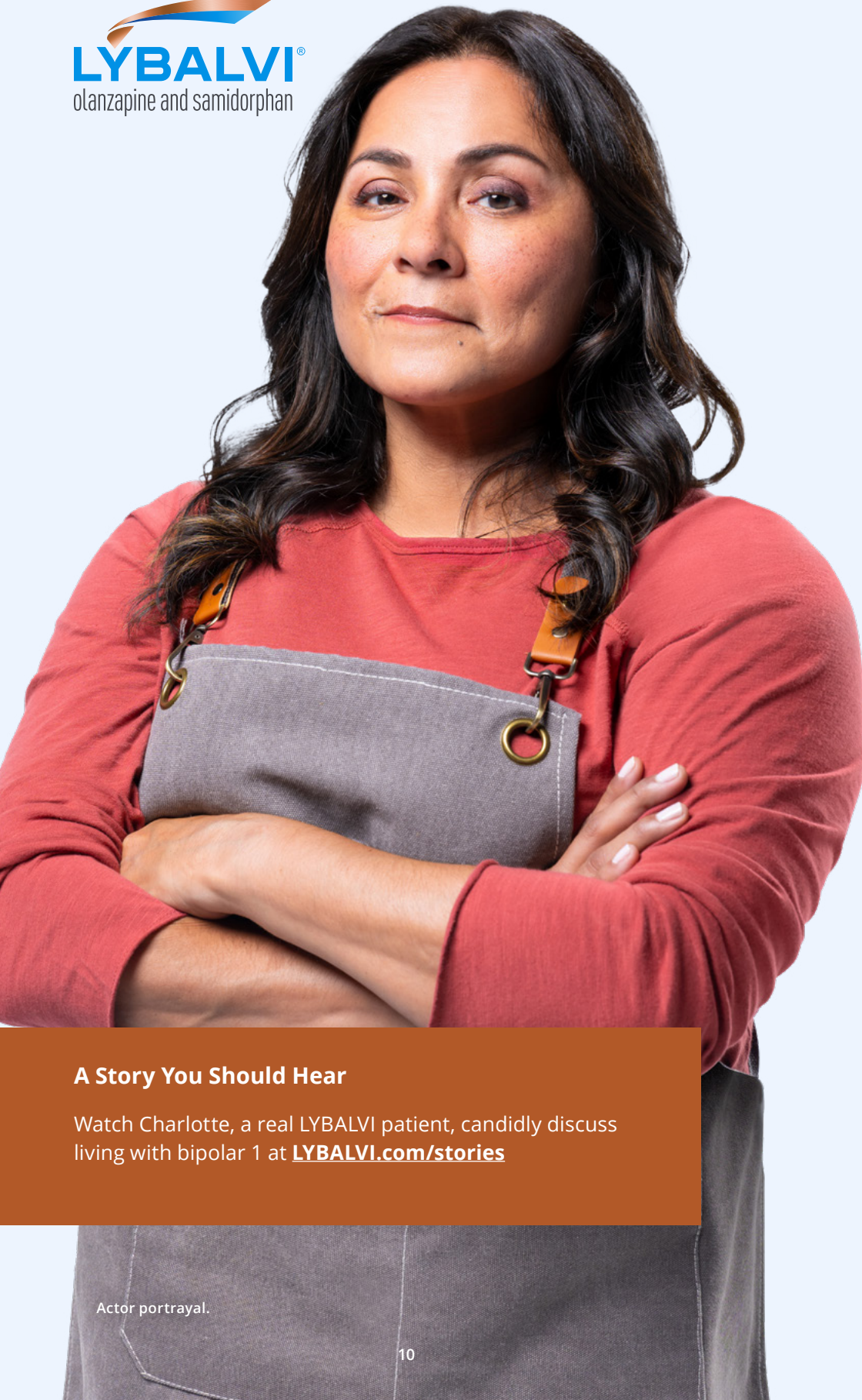


Actor portrayal.

Things to avoid while taking LYBALVI:

- **Do not** drive a car, operate machinery, or do other dangerous activities until you know how LYBALVI affects you. LYBALVI may make you feel drowsy
- Avoid drinking alcohol during treatment with LYBALVI
- Avoid getting over-heated or dehydrated while taking LYBALVI
 - **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

Please see additional Important Safety Information throughout and full Prescribing Information, including Boxed Warning and Medication Guide.



A Story You Should Hear

Watch Charlotte, a real LYBALVI patient, candidly discuss living with bipolar 1 at [LYBALVI.com/stories](https://www.lybalvi.com/stories)

LYBALVI[®] is a once-daily pill taken by mouth alone or in combination with lithium or valproate

Everyone is different. Your healthcare provider may adjust your dose based on your response to LYBALVI. It's important for you to take LYBALVI exactly as your healthcare provider tells you, and not to change your dose or stop taking LYBALVI without talking to them first.

Take LYBALVI exactly as your healthcare provider tells you to take it.



Do not change the dose or stop taking LYBALVI without first talking to your healthcare provider



Take by mouth once a day (in clinical studies, people were encouraged to take LYBALVI at bedtime)



Take with or without food



Swallow LYBALVI tablets whole. **Do not** split or combine different strength LYBALVI tablets

Do not take LYBALVI if you are taking opioids or are experiencing acute opioid withdrawal. For more information about the effect of LYBALVI on opioids, see pages [12](#) & [13](#).

Important Safety Information (cont'd)

You or someone close to you should get emergency medical help right away if you:

- have trouble breathing
- become very drowsy with slowed breathing
- have slow, shallow breathing (little chest movement with breathing)
- feel faint, very dizzy, confused, or have unusual symptoms

Tell your healthcare provider if you are taking LYBALVI before a medical procedure or surgery.

Please see additional Important Safety Information throughout and full Prescribing Information, including Boxed Warning and Medication Guide.

LYBALVI[®] can increase your chance of having opioid withdrawal or opioid overdose

Opioid withdrawal. **Do not** take LYBALVI for at least 7 days after you stopped taking short-acting opioids and for at least 14 days after you stopped taking long-acting opioids. One of the medicines in LYBALVI (samidorphan) can cause opioid withdrawal that may be severe and cause hospitalization in people who are physically dependent on opioids. Talk to your healthcare provider if you have questions about the type of opioid you take.

Risk of life-threatening opioid overdose. You should not start taking opioids for at least 5 days after you stop treatment with LYBALVI. One of the medicines in LYBALVI (samidorphan) can increase your chance of having an opioid overdose that can cause death if you take opioids during treatment or within 5 days after stopping treatment with LYBALVI.

You can accidentally overdose in 2 ways:

- LYBALVI blocks the effects of opioids, such as heroin, methadone, or opioid pain medicines. **Do not** take large amounts of opioids to try to overcome the opioid-blocking effects of LYBALVI. This can lead to serious injury, coma, or death.
- After you take LYBALVI, its blocking effect slowly decreases and completely goes away over time. You may be more sensitive to the effects of opioids. If you have used opioid street drugs or opioid-containing medicines in the past, using opioids in amounts that you used before treatment with LYBALVI can lead to overdose or death.

It is important that you tell your family and the people closest to you of this increased sensitivity to opioids and the risk of overdose.

Please see additional Important Safety Information throughout and full Prescribing Information, including Boxed Warning and Medication Guide.



You or someone close to you should get emergency medical help right away if you:

- Have trouble breathing
- Become very drowsy with slowed breathing
- Have slow, shallow breathing (little chest movement with breathing)
- Feel faint, very dizzy, confused, or have unusual symptoms

Tell your healthcare provider if you are taking LYBALVI before a medical procedure or surgery.

Examples of opioids that should not be taken with LYBALVI include:

- Buprenorphine-containing medicines
- Codeine-containing medicines
- Fentanyl
- Heroin
- Opium
- Illicit street drugs containing opioids
- Hydrocodone-containing medicines
- Hydromorphone
- Meperidine
- Methadone
- Morphine
- Oliceridine
- Opioid pain medicines
- Oxycodone
- Tramadol-containing medicines

This list is meant to provide examples and is not a complete list of opioids. Talk to your healthcare provider for additional information about opioids.

Important Safety Information (cont'd)

- **Neuroleptic malignant syndrome (NMS), 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
- sweating
- stiff muscles
- changes in your breathing, pulse, heart rate, and blood pressure
- confusion

- **Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS):** One of the medicines in LYBALVI[®] (olanzapine) can cause DRESS, which can cause death. Tell your healthcare provider right away if you develop any of the following symptoms of DRESS, including:

- rash
- fever
- swollen glands
- kidney problems
- liver problems
- lung problems
- heart problems

- **Problems with your metabolism such as:**

- **high blood sugar (hyperglycemia) and diabetes.** Increases in blood sugar can happen in some people who take LYBALVI. Extremely high blood sugar can lead to coma or death. Your healthcare provider should check your blood sugar before you start and regularly during treatment with LYBALVI.

Call your healthcare provider if you have any of these symptoms of high blood sugar during treatment with LYBALVI:

- feel very thirsty
- need to urinate more than usual
- feel very hungry
- feel weak or tired
- feel sick to your stomach
- 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 and regularly during treatment with LYBALVI.

- **weight gain.** You and your healthcare provider should check your weight before you start and often during treatment with LYBALVI.

- **Uncontrolled body movements (tardive dyskinesia).**

LYBALVI 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 LYBALVI. Tardive dyskinesia may also start after you stop taking LYBALVI.

- **Decreased blood pressure (orthostatic hypotension) and fainting.** You may feel lightheaded or faint when you rise too quickly from a sitting or lying position.

- **Falls.** LYBALVI 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.

- **Low white blood cell count.** Your healthcare provider may do blood tests during the first few months of treatment with LYBALVI.

- **Difficulty swallowing** that can cause food or liquid to get into your lungs.

- **Seizures (convulsions).**

- **Problems controlling your body temperature so that you feel too warm.**

- **Increased prolactin levels in your blood.** Your healthcare provider may do blood tests to check your prolactin levels during treatment with LYBALVI.

The most common side effects of LYBALVI when used to treat people with schizophrenia include:

- weight gain
- sleepiness
- dry mouth
- headache

The most common side effects of LYBALVI when used alone to treat people with mixed or manic episodes that happen with bipolar I disorder include:

- weakness
- dry mouth
- constipation
- increased appetite
- sleepiness
- dizziness
- shaking

The most common side effects of LYBALVI when used in combination with lithium or valproate to treat people with mixed or manic episodes that happen with bipolar I disorder include:

- dry mouth
- weight gain
- increased appetite
- dizziness
- back pain
- constipation
- problems speaking
- mouth watering
- memory problems
- numbness and tingling in your arm and legs

(continued)

Important Safety Information (cont'd)

Do not drive a car, operate machinery, or do other dangerous activities until you know how LYBALVI[®] affects you. LYBALVI may make you feel drowsy.

Avoid drinking alcohol during treatment with LYBALVI.

Avoid getting over-heated or dehydrated.

- **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.

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

- have or had heart problems or a stroke
- use or abuse street (illegal) drugs
- have or had low or high blood pressure
- have kidney problems
- have diabetes or high blood sugar or a family history of diabetes or high blood sugar
- have or have had high levels of total cholesterol, LDL cholesterol, or triglycerides or low levels of HDL cholesterol
- have or had a low white blood cell count
- have problems swallowing
- have or had seizures (convulsions)
- have or had problems with urination or prostate problems
- have or had breast cancer
- have or had constipation or a bowel obstruction
- have or had high prolactin levels
- are pregnant or plan to become pregnant. Talk to your healthcare provider about the risks to you and your unborn or newborn baby if you take LYBALVI during pregnancy.
 - Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with LYBALVI.
 - If you become pregnant during treatment with LYBALVI, 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 visit <http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/>

- are breastfeeding or plan to breastfeed. LYBALVI passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with LYBALVI.

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

LYBALVI and other medicines may affect each other causing possible serious side effects.

LYBALVI may affect the way other medicines work, and other medicines may affect how LYBALVI works.

Especially tell your healthcare provider if you:

- take opioids or have stopped taking opioids in the past 14 days
- take or plan to take other olanzapine containing medicines

Your healthcare provider can tell you if it is safe to take LYBALVI with your other medicines. **Do not** start or stop any medicines while taking LYBALVI without first talking to your healthcare provider.

Tell your healthcare provider if you take a urine drug screening test because LYBALVI may affect your test results. Tell those giving the drug screening test that you are taking LYBALVI.

These are not all the possible side effects of LYBALVI.

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

Please see full Prescribing Information, including Boxed Warning and Medication Guide.



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GET HELP TO **PUSH BACK** AGAINST BIPOLAR 1

Ask your healthcare provider about **LYBALVI**[®]

Visit [LYBALVI.com](https://www.lybalvi.com) to learn more.

Individual results may vary.

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