

A treatment that helps you

**PUSH BACK**

against

**BIPOLAR I**

**LYBALVI**<sup>®</sup>  
olanzapine and samidorphan  
5 mg/10 mg -10 mg/10 mg -15 mg/10 mg  
20 mg/10 mg tablets



Actor portrayal.

## Indications and Important Safety Information

LYBALVI<sup>®</sup> is a prescription medicine which contains 2 medicines (olanzapine and samidorphan) used in adults:

- to treat schizophrenia
- 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

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 inside and full Prescribing Information, including Boxed Warning and Medication Guide.**

We know it's important to find a treatment option that works for you

Get to know LYBALVI and talk to your healthcare provider about whether it may be an option for you

LYBALVI can help reduce BD-1 symptoms as measured by the Young Mania Rating Scale (Y-MRS), one of the most frequently used rating scales to assess manic symptoms. The Y-MRS combines scores from the following:

- Elevated mood
- Increased energy
- Sexual interest
- Sleep
- Irritability
- Speech
- Language/disordered thoughts
- Thought content—grandiosity (feeling overly important), paranoia, delusions, or hallucinations
- Disruptive or aggressive behavior
- Appearance
- Insight into mental illness



Actor portrayals.

## Important Safety Information (continued)

**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.

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

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LYBALVI contains olanzapine, which has been proven to reduce manic or mixed episodes

### LYBALVI may help to reduce symptoms of bipolar 1 disorder in adults

In one study, half of the adults taking one of the ingredients of LYBALVI, olanzapine, went more than 2 times longer without relapsing or being hospitalized, compared with half of the adults who took a placebo (sugar pill).



In this study, patients with manic or mixed episodes of bipolar 1 disorder who had responded to olanzapine for 2 weeks were continued on olanzapine or placebo (sugar pill) and observed for relapse. 225 patients received olanzapine and 136 patients received placebo. Relapse was defined as an increase in symptoms on 2 standard surveys, or being hospitalized for either mania or depression.

## Important Safety Information (continued)

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.

## Important Safety Information (continued)

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.

**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 and full Prescribing Information, including Boxed Warning and Medication Guide.**

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

- Buprenorphine-containing products
- Codeine
- Fentanyl
- Heroin and opium (illicit street drugs)
- Hydrocodone-containing products
- Hydromorphone
- Meperidine
- Methadone
- Morphine
- Oliceridine
- Opioid pain medicines
- Oxycodone-containing products
- Tramadol

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

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## LYBALVI can be used for the treatment of manic or mixed episodes:



by itself



together with lithium or valproate



as a maintenance therapy, meaning it can be used every day to help reduce symptoms on an ongoing basis



Take LYBALVI exactly as your healthcare provider tells you to take it. **Do not** change the dose or stop taking LYBALVI yourself.

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

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

**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

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

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 talking to your doctor first.

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



Actor portrayal.

## Important Safety Information (continued)

LYBALVI may cause serious side effects, including:

- **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

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20 mg/10 mg tablets

## How to take LYBALVI

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

LYBALVI is a single tablet taken by mouth once a day. **Do not** change the dose or stop taking LYBALVI without first talking to your healthcare provider.



LYBALVI can be taken with or without food.



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



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.

If you take too much LYBALVI, call your Poison Control Center at **1-800-222-1222** or go to the nearest hospital emergency room right away.

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

#### Tell your healthcare provider:

- About any healthcare conditions you may have, including if you are pregnant, plan to become pregnant, or are breastfeeding. Talk to your healthcare provider about the risks to you and your unborn or newborn baby if you take LYBALVI during pregnancy
- About all medications you take, including prescription and over-the-counter drugs, vitamins, and herbal supplements
- If you take opioids or have stopped taking opioids in the past 14 days
- If you take or plan to take other olanzapine-containing medicines



Other dosage strengths available

## Important Safety Information (continued)

### LYBALVI may cause serious side effects, including:

- **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
  - 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 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.

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

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## Things to avoid while taking LYBALVI

It's important to be open and honest with your doctor about opioid use



**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



Actor portrayal.

## Important Safety Information (continued)

LYBALVI may cause serious side effects, including:

- **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.

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

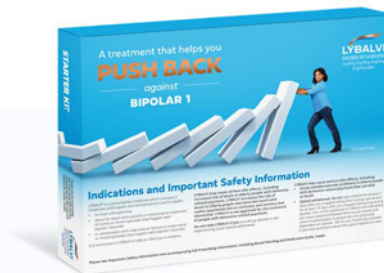
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## Talking with your doctor about LYBALVI



Actor portrayals.

Your starter kit, which you can receive from your doctor, includes additional tools to help you as you start taking LYBALVI



### Discussion Guide

- This guide may help you prepare for conversations with your doctor about LYBALVI at your next appointment.



### Journal

- Mental health professionals and people living with mental illness report that keeping a journal may help manage mental health. This journal can help you record information that can be shared with your doctor.



### Patient Safety Card

- 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; or 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.
- Always carry the Patient Safety Card with you while being treated with LYBALVI. This card is intended to inform healthcare providers that you are taking LYBALVI, so it's important to show it when you visit a doctor or go to the emergency room for treatment.

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

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## You may be able to save

If you have commercial insurance and are eligible for the LYBALVI® Co-pay Savings Program, you can get the co-pay savings card, which makes you eligible to pay \$0 for your first 3 fills of LYBALVI.\*

After 3 fills, each refill may cost as little as \$20, with maximum savings of \$450 per 30-day supply.\*

For more information, call 1-855-820-9624  
to speak with a representative,  
Monday through Friday, 8 AM to 8 PM ET.



If you lose your co-pay card, you can visit [LYBALVI.com/copay](https://www.lybalvi.com/copay) to download a new one.

Visit [LYBALVI.com/copay](https://www.lybalvi.com/copay) to learn more about the LYBALVI® Co-pay Savings Program, or go to [LYBALVI.com](https://www.lybalvi.com)

\*Maximum savings limit applies; patients' out-of-pocket expenses may vary. Maximum 30-day supply per fill for the first 3 fills. Beginning at fill 4, a maximum savings of \$450 per 30-day supply will be provided towards the cost of the LYBALVI prescription. Health plan requirements for a prior authorization and/or step therapies must be attempted prior to using this co-pay offer. Patient must be 18 years of age or older and have a prescription for LYBALVI. Offer not valid for patients enrolled in Medicare, Medicaid, or other federal or state healthcare programs. Offer not valid for cash paying patients. Please see full Program Terms and Conditions.

**Eligibility for Alkermes-sponsored Co-pay Savings:** This offer is only available to commercially insured patients 18 years or older with a LYBALVI prescription that is consistent with the Prescribing Information. Health plan requirements for a prior authorization and/or step therapies must be attempted prior to using this co-pay offer. This offer is not available to patients who are enrolled in, or covered by, any local, state, federal or other government program that pays for any portion of medication costs, including but not limited to Medicare, including Medicare Part D or Medicare Advantage plans; Medicaid, including Medicaid Managed Care and Alternative Benefit Plans under the Affordable Care Act; Medigap; VA; DOD; TRICARE; or a residential correctional program. Patients who become eligible for any government program that pays for any portion of medication costs will no longer be eligible for this program.

**Authorization and Additional Terms of Use:** By using this offer, you authorize the LoyaltyScript® 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 LYBALVI prescription by your health insurance plan. This offer is not conditioned on any past, present, or future purchase, including refills. Alkermes reserves the right to rescind, revoke, or amend this offer, program eligibility, and requirements at any time without notice. This offer is limited to one per patient, may not be used with any other offer, is not transferable, and may not be sold, purchased or traded, or offered for sale, purchase, or trade. Void where prohibited by law. Program may be subject to plan benefit design requirements. Program Administrator or its designee will have the right upon reasonable prior written notice, during normal business hours, and subject to applicable law, to audit compliance with this program.



## Important Safety Information (continued)

LYBALVI may cause serious side effects, including:

- **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.

Please see additional [Important Safety Information](#) and full [Prescribing Information](#), including [Boxed Warning](#) and [Medication Guide](#).

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20 mg/10 mg tablets



## Possible side effects

### It's natural to have questions about possible side effects when starting a new medicine

LYBALVI may cause serious side effects including:

- stroke
- opioid withdrawal
- risk of opioid overdose
- neuroleptic malignant syndrome
- drug reaction with eosinophilia and systemic symptoms
- problems with your metabolism
  - high blood sugar (hyperglycemia) and diabetes
  - weight gain
  - increased fat levels (cholesterol and triglycerides) in the blood
- uncontrolled body movements
- decreased blood pressure and fainting
- falls
- low white blood cell count
- difficulty swallowing
- seizures
- problems controlling your body temperature so that you feel too warm
- increased prolactin levels

If you have any questions about your health or medicines, talk to your healthcare provider. You are encouraged to report all side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

Actor portrayals.

## Important Safety Information (continued)

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

- weight gain
- dry mouth
- sleepiness
- 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
- constipation
- sleepiness
- shaking
- dry mouth
- increased appetite
- dizziness

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## Consider your overall health

Before starting LYBALVI, talk with your doctor about any medical conditions you have and any medicines you take or recently have taken

Mental health conditions and the medicines used to treat them can affect your health. Additionally, people who live with bipolar 1 disorder may have other health conditions, such as certain respiratory diseases, infectious diseases, and cardiovascular diseases. Therefore, it's important to talk to your doctor about your overall health.



Talk to your doctor about:



staying active



eating healthy foods



getting enough sleep



avoiding smoking



avoiding alcohol



avoiding drug use



Actor portrayals.

## Important Safety Information (continued)

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

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## You're not alone

### Advocacy and support groups can offer additional help or resources

There are many organizations that can help you on your journey.

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

nami.org  
1-800-950-NAMI (6264)

#### Depression and Bipolar Support Alliance (DBSA)

dbsalliance.org  
1-800-826-3632

#### Mental Health America (MHA)

mhanational.org  
1-800-969-6642

Alkermes is not affiliated with and does not endorse any of these third-party organizations.

**Talk to your doctor about LYBALVI.**



Actor portrayals.

## Important Safety Information (continued)

**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.

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

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## Indications and Important Safety Information

LYBALVI is a prescription medicine which contains 2 medicines (olanzapine and samidorphan) used in adults:

- to treat schizophrenia
- 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

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.**

**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.

- **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.

**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.

- **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
  - stiff muscles
  - confusion
  - sweating
  - changes in your breathing, pulse, heart rate, and blood pressure
- **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
  - swollen glands
  - liver problems
  - heart problems
  - fever
  - kidney problems
  - lung 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
- 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 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.



## Important Safety Information (continued)

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

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

**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.

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.**



# PUSH BACK

against

## BIPOLAR 1



Actor portrayal.

Ask your healthcare provider  
about LYBALVI®

- Commercially insured eligible patients may be able to save with the LYBALVI® Co-pay Savings Program

See terms and conditions on page 14.

Learn more at [LYBALVI.com](https://www.lybalvi.com)

## Important Safety Information

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](#) inside and full [Prescribing Information](#), including [Boxed Warning](#) and [Medication Guide](#).



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LYBALVI®  
olanzapine and samidorphan  
5 mg/10 mg - 10 mg/10 mg - 15 mg/10 mg  
20 mg/10 mg tablets