

BRIXADI for opioid addiction

Learn about a treatment that can help you on your recovery journey

What is BRIXADI?

BRIXADI is a prescription medicine used to treat moderate to severe opioid addiction (dependence) to opioid drugs (prescription or illegal) in people:

 who have started treatment with a single dose of a buprenorphine medicine in the form of a sublingual tablet or buccal film (transmucosal),

OR

who are already being treated with buprenorphine

BRIXADI should be used as part of a complete treatment plan that also includes counseling and behavioral therapy.

IMPORTANT SAFETY INFORMATION

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

- Because of the serious risk of potential harm or death from self-injecting BRIXADI into a vein (intravenously), it is only available through a restricted program called the BRIXADI Risk Evaluation and Mitigation Strategy (REMS) Program.
 - BRIXADI is not available in retail pharmacies.
 - Your BRIXADI injection will only be given to you by a healthcare provider.



Having an addiction can be hard. You may even blame yourself.

Opioid addiction is a brain disease.

But there is hope for recovery. BRIXADI and counseling can help reduce your drug use.



BRIXADI can cause serious and life-threatening breathing problems

Get emergency help right away if you feel faint, feel dizzy, are confused, feel sleepy or uncoordinated, have blurred vision, have slurred speech, are breathing slower than normal, and/or cannot think well or clearly.



Why BRIXADI?

BRIXADI is a medicine that can help you treat your opioid addiction, also called opioid use disorder (OUD).



BRIXADI is a shot (injection) given by your healthcare provider. It gives you a week, or a month, of medicine in 1 injection.



Once under your skin, it becomes a gel that you may not feel.



The gel releases the medicine, called buprenorphine, into your body at a steady rate. This means that the medicine is released all week or month without daily ups and downs.

Do not take BRIXADI with certain medicines

Taking BRIXADI with other opioid medicines, benzodiazepines, alcohol, other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.



Who is **BRIXADI** for?

If your healthcare team said you have moderate to severe OUD, BRIXADI may be an option if:

- You are taking a medicine for OUD called buprenorphine as a tablet or film. In that case, you can switch directly to BRIXADI
- You are not taking buprenorphine. In that case, you will receive a tablet or film of buprenorphine as a test dose before starting BRIXADI

Ask your healthcare team about starting or switching to BRIXADI.

Who should not receive BRIXADI?

Do not receive BRIXADI if you are allergic to buprenorphine or any ingredients in BRIXADI. See the BRIXADI Medication Guide for a list of ingredients in BRIXADI.

Before receiving BRIXADI, tell your healthcare team about all of your medical conditions.



How is BRIXADI given?

BRIXADI is an injection that can be received once a week or once a month.

This means you don't have to worry about taking it every day.



There are also different dose strengths of BRIXADI.

Different dose strengths mean your healthcare team can decide the dose that is right for you.

Your BRIXADI injection will be given to you by your healthcare team.

BRIXADI will be injected under the skin (subcutaneously) into your leg, stomach, butt, or upper arm. If you are new to buprenorphine treatment, the upper arm should only be used after 4 doses.

- BRIXADI is injected using a small needle
- Patients in the studies had mild to moderate reactions where the shot was given. None of the reactions were severe



BRIXADI can cause serious side effects, including:

Trouble breathing; sleepiness, dizziness, and problems with coordination; physical dependence or abuse; liver problems; allergic reaction; opioid withdrawal; and decrease in blood pressure.

(buprenorphine) extended-release injection for subcutaneous use (1) Weekly 8-16-24-32 mg Monthly 64-96-128 mg

BRIXADI can help treat your disease

Remember that OUD is not your fault. It's an illness that requires treatment. BRIXADI can help you on your recovery journey.

- It is a shot given once a week or once a month
- It becomes a gel under your skin and releases medicine at a steady rate
- BRIXADI and counseling can help you reduce your drug use

Talk with your healthcare team about the next steps in your treatment.

The most common side effects of BRIXADI include:

Injection site pain, headache, constipation, nausea, injection site redness, injection site itching, trouble sleeping (insomnia), and urinary tract infection.

Important Safety Information

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

- Because of the serious risk of potential harm or death from self-injecting BRIXADI into a vein (intravenously), it is only available through a restricted program called the BRIXADI Risk Evaluation and Mitigation Strategy (REMS) Program.
 - BRIXADI is not available in retail pharmacies.
 - Your BRIXADI injection will only be given to you by a healthcare provider.
- BRIXADI (buprenorphine) extended-release injection for subcutaneous use contains a medicine called buprenorphine. Buprenorphine is an opioid that can cause serious and lifethreatening breathing problems, especially if you take or use certain other medicines or drugs.
- Talk to your healthcare provider about naloxone. Naloxone is a medicine that is available to patients for the emergency treatment of an opioid overdose. If naloxone is given, you must call 911 or get emergency medical help right away to treat an overdose or accidental use of an opioid.

BRIXADI can cause serious and life-threatening breathing problems. Get emergency help right away if you:

- feel faint
- feel dizzy
- are confused
- feel sleepy or uncoordinated
- have blurred vision
- have slurred speech
- are breathing slower than normal
- · cannot think well or clearly
- Do not take BRIXADI with certain medicines. Taking BRIXADI with other opioid medicines, benzodiazepines, alcohol, other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.
- In an emergency, have family members tell the emergency department staff that you are physically dependent on an opioid and are being treated with BRIXADI.
- You may have detectable levels of BRIXADI in your body for several months after stopping treatment with BRIXADI.



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Important Safety Information (Continued)

Do not receive BRIXADI if you are allergic to buprenorphine or any ingredients in BRIXADI:

- BRIXADI weekly: anhydrous ethanol, soybean phosphatidylcholine, glycerol dioleate
- BRIXADI monthly: N-methylpyrrolidone, soybean phosphatidylcholine, glycerol dioleate

Before receiving BRIXADI, tell your healthcare provider about all of your medical conditions, including if you have:

- Trouble breathing or lung problems
- A curve in your spine that affects your breathing
- Addison's disease
- An enlarged prostate (men)
- Problems urinating
- Liver, kidney, or gallbladder problems
- A history of alcoholism
- A head injury or brain problem
- Mental health problems
- Adrenal gland or thyroid gland problems
- A latex allergy. The BRIXADI needle cap contains latex.

Tell your healthcare provider if you are:

- pregnant or plan to become pregnant. If you receive BRIXADI
 while pregnant, your baby may have symptoms of opioid
 withdrawal at birth that could be life-threatening if not
 recognized and treated. Talk to your healthcare provider if you
 are pregnant or become pregnant.
- breastfeeding. BRIXADI can pass into your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby during treatment with BRIXADI. Monitor your baby for increased drowsiness and breathing problems if you breastfeed during treatment with BRIXADI.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Talk with your healthcare provider before starting any new medicines during or after stopping treatment with BRIXADI.

What should I avoid while receiving BRIXADI?

 Do not drive, operate heavy machinery or perform any other dangerous activities until you know how BRIXADI affects you. BRIXADI can cause drowsiness and slow reaction times. BRIXADI can make you sleepy, dizzy, or lightheaded. This may happen more often in the first few days after your injection and when your dose is being changed.

Important Safety Information (Continued)

• You should not drink alcohol or use prescription or over-thecounter medicines that contain alcohol during treatment with BRIXADI, because this can lead to loss of consciousness or even death.

What are the possible side effects of BRIXADI?

BRIXADI can cause serious side effects, including:

- Trouble breathing. Taking BRIXADI with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants can cause breathing problems that can lead to coma and death.
- Sleepiness, dizziness, and problems with coordination.
- Physical dependence or abuse.
- Liver problems. Call your healthcare provider right away if you notice any of these symptoms:
 - your skin or the white part of your eyes turns yellow (jaundice)
 - dark or "tea-colored" urine
 - light-colored stools (bowel movements)
 - loss of appetite
 - pain, aching, or tenderness on the right side of your stomach area
 - nausea

Your healthcare provider should do tests to check your liver before and during treatment with BRIXADI.

- Allergic reaction. You may have a rash, hives, swelling of your face, wheezing, light-headedness when changing positions, feeling faint, or loss of consciousness. Call your healthcare provider or get emergency help right away.
- **Opioid withdrawal.** Call your healthcare provider right away if you get any of these symptoms:
 - shaking
 - sweating more than normal
- watery eyes
- goose bumps
- diarrhea
- feeling hot or cold more than normal
- vomiting
- muscle aches

runny nose

These symptoms may start weeks to months after your last dose of BRIXADI. Tell your healthcare provider if you develop any of these symptoms.

• **Decrease in blood pressure.** You may feel dizzy if you get up too fast from sitting or lying down.

Important Safety Information (Continued)

• The most common side effects of BRIXADI include: injection site pain, headache, constipation, nausea, injection site redness, injection site itching, trouble sleeping (insomnia), and urinary tract infection.

BRIXADI may affect fertility in males and females. Talk to your healthcare provider if this is a concern for you.

These are not all the possible side effects of BRIXADI. Call your healthcare provider for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For more information about BRIXADI, ask your healthcare provider or go to www.BRIXADI.com or call 1-833-274-9234.

This information does not take the place of talking with your healthcare provider for medical advice about your condition or treatment.

Please see the BRIXADI Medication Guide and Full Prescribing Information, including Boxed Warning, at BRIXADI.com or accompanying this document.