

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.



Opioid addiction is a disease, not a choice or personal failure

No matter where you are on your recovery journey, BRIXADI may be an option for you.



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 team. It gives you a month or a week 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. The medicine is slowly released all month or week without daily ups and downs.

Ask your healthcare team about starting or switching to BRIXADI.

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 you have moderate to severe opioid addiction, BRIXADI may be right for you if:

- You are taking medicine called buprenorphine for opioid addiction as a daily 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



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?



Your healthcare team will give you your injection of BRIXADI either once a month or once a week.



There are different dose strengths of BRIXADI. Your healthcare team can decide what dose will work best for you.



BRIXADI is injected under the skin using a small needle.

Areas where BRIXADI can be injected

BRIXADI can be injected under the skin in different areas of your body: butt, leg, stomach, or upper arm. You and your healthcare team can determine which of these injection areas works best for you.



 Patients in the study 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.



Key points to remember:

- BRIXADI with counseling may help lower drug use
- BRIXADI is a shot given once a month or once a week
- BRIXADI slowly releases medicine during the whole month or week. This means that you may not have daily ups and downs

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.

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 - 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 life-threatening 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.



IMPORTANT SAFETY INFORMATION (Continued)

- 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.

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.

IMPORTANT SAFETY INFORMATION (Continued)

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.
- You should not drink alcohol or use prescription or over-the-counter 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.

IMPORTANT SAFETY INFORMATION (Continued)

- 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
 - feeling hot or cold more than normal
 - runny nose

- watery eyes
- goose bumps
- diarrhea
- vomiting
- muscle aches

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.
- 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.