

Brixadi[®]
(buprenorphine) extended-release
injection for subcutaneous use 
Weekly 8 • 16 • 24 • 32 mg **Monthly** 64 • 96 • 128 mg

Getting started with BRIXADI

Find help preparing for the next
step in your recovery journey



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.



Scan the QR code for more
information and resources
at [BRIXADI.com](https://www.brixadi.com).

Please see the [BRIXADI Medication Guide](#) and [Full Prescribing Information](#), including Boxed Warning, at [BRIXADI.com](https://www.brixadi.com) or accompanying this document.

Opioid addiction is not a choice, but your journey toward recovery is

About opioid use disorder (OUD)

OUD, sometimes called opioid addiction, is a chronic disease that can affect anyone. Opioids trigger an intense rush of dopamine, a reward chemical, to be released in the brain. Over time, with OUD, your brain craves the dopamine rush you experience when using opioids. You may also have withdrawal symptoms when you aren't taking opioids.

Getting help to get better

Getting better starts with seeking help. OUD can be managed with medicine prescribed by a healthcare provider just like other chronic conditions, such as heart disease, asthma, or diabetes. That's why medicine prescribed by a healthcare provider, in addition to counseling, is so important.

Buprenorphine treatment for OUD

A common medicine that is used to treat OUD is called buprenorphine. Buprenorphine can block the effects of opioids. It is available in 2 forms:

- **Daily oral (taken by mouth as a dissolvable tablet or film)**
- **Long-acting injection**



Studies show that the combination of medicine and counseling increases your chance for a successful recovery.

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.

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

Important Safety Information (Continued)

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

- 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.

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

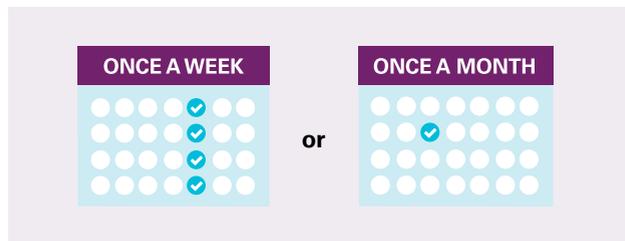
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About BRIXADI

BRIXADI is an injection that contains the medicine buprenorphine. Buprenorphine has been used to treat OUD for many years. It can help reduce opioid use by blocking the rewarding effects of opioids.

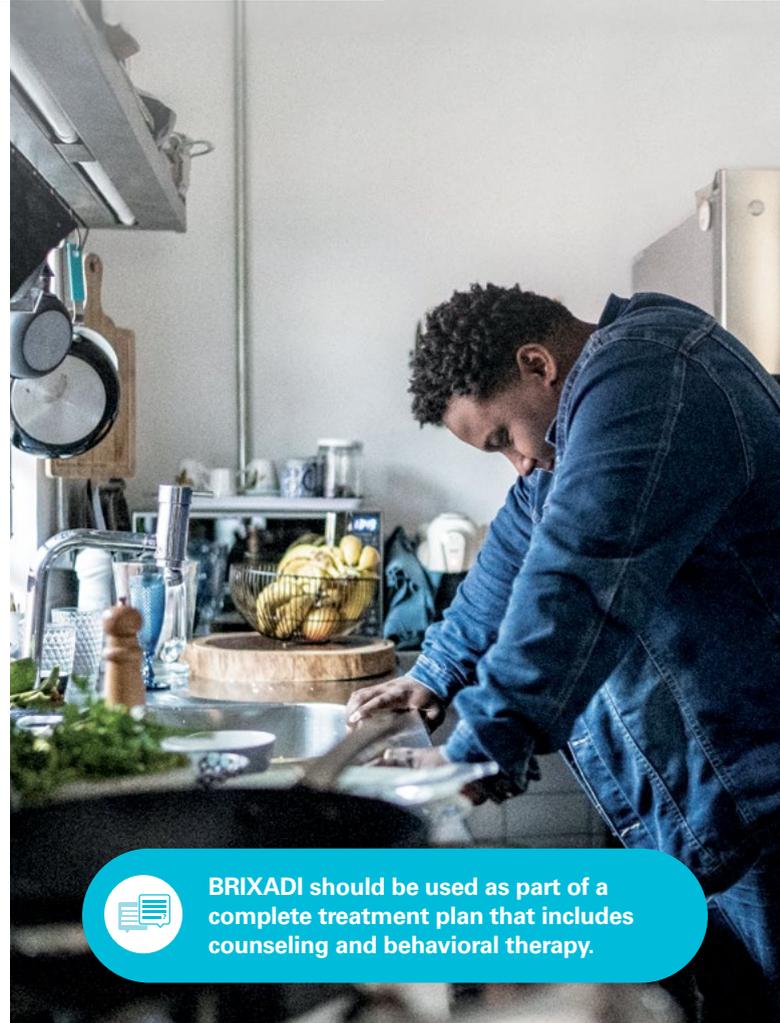
Dosing options with BRIXADI

BRIXADI is available in once-a-week and once-a-month doses. The medicine is steadily released in your body throughout the entire week or month. You and your healthcare provider can choose which dose is right for you.



Who can take BRIXADI?

- If you are already taking buprenorphine for OUD, such as a daily dissolvable tablet or film, you can switch directly to an injection with BRIXADI
- If you are not currently taking a buprenorphine treatment for OUD, your healthcare provider will give you a test dose of buprenorphine as a dissolvable tablet or film before starting you on a weekly injection of BRIXADI



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

Important Safety Information (Continued)

- **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.
- Do not receive BRIXADI** if you are allergic to buprenorphine or any ingredients in BRIXADI:
- BRIXADI weekly: anhydrous ethanol, soybean phosphatidylcholine, glycerol dioleate

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



With BRIXADI, you won't need to take buprenorphine each day. You won't have to pick it up at the pharmacy or remember to bring it to work or when you travel.



BRIXADI was studied in 428 patients. These patients were using heroin, fentanyl, or other opioids. BRIXADI helped patients reduce illicit opioid use. The safety profile of BRIXADI was generally comparable to oral buprenorphine except for injection site reactions. No injection site reactions were reported as being severe.



Weekly and monthly dosing options and different dose strengths let you and your healthcare provider create a medication plan that fits your needs.



If you are currently taking certain doses of oral buprenorphine, you may be able to switch directly to BRIXADI.



You won't have to store BRIXADI in your home, and if you have children, you won't have to worry that they may find it by accident.

Important Safety Information (Continued)

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

- 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.

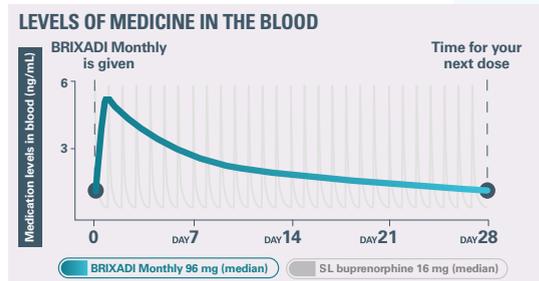
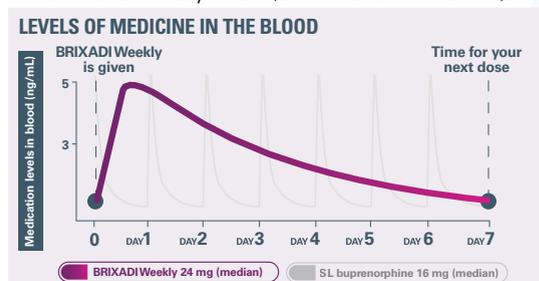
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How does BRIXADI work?

BRIXADI is injected as a liquid just under the skin (subcutaneously) by your healthcare provider. After the injection, BRIXADI changes to a gel form called a depot. The depot is not always felt under the skin. The depot slowly releases buprenorphine into your body throughout the entire week or month at a steady rate. This means that you may not have daily ups and downs with BRIXADI.

Buprenorphine is released at a steady rate

The graphs below show the level of buprenorphine in the blood at steady state (after 4 doses in a row).



SL, sublingual (under the tongue).
Model based on 236 subjects and greater than 10,000 observations from 4 clinical studies.

Important Safety Information (Continued)

Tell your healthcare provider if you are:

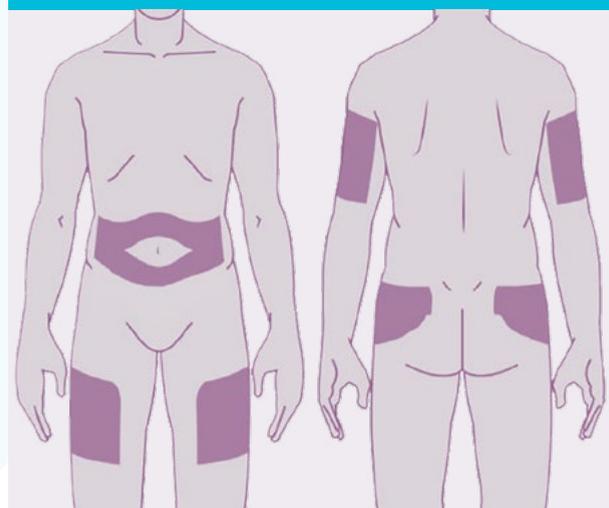
- **pregnant or plan to become pregnant.** If you receive BRIXADI while pregnant, your baby may have symptoms of opioid withdrawal at birth that could be life-threatening if not recognized and treated. Talk to your healthcare provider if you are pregnant or become pregnant.
- **breastfeeding.** BRIXADI 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.

How will I receive BRIXADI?

Your healthcare provider will inject the medicine with a small needle just under the skin (subcutaneously) in one of the following areas: buttock, thigh, stomach (abdomen), or upper arm.

- For BRIXADI Weekly, your healthcare provider will need to rotate sites between injections
- If you are new to buprenorphine treatment, the upper arm area should only be used after 4 consecutive doses (once steady state has been achieved)

Where BRIXADI is injected



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.

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BRIXADI dosing options equivalent to oral buprenorphine doses

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Daily Sublingual Buprenorphine Dose*	BRIXADI Weekly	BRIXADI Monthly
Less than or equal to 6 mg	8 mg	-
8-10 mg	16 mg	64 mg
12-16 mg	24 mg	96 mg
18-24 mg	32 mg	128 mg

*One SUBOXONE® (buprenorphine and naloxone) 8 mg/2 mg sublingual tablet provides equivalent buprenorphine exposure to one SUBUTEX® (buprenorphine HCl) 8 mg sublingual tablet or one Zubsolv® (buprenorphine and naloxone) 5.7 mg/1.4 mg sublingual tablet.



Remember to talk with your healthcare provider about how you are feeling while on BRIXADI or if you have concerns or questions.

Important Safety Information (Continued)

What should I avoid while receiving BRIXADI? (continued)

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.**

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

What else should I know about BRIXADI?

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Do I have to experience withdrawal before switching from oral buprenorphine to BRIXADI?

Withdrawal is not required to switch from oral buprenorphine to BRIXADI. Speak to your healthcare provider if you have concerns about withdrawal when switching from oral buprenorphine to BRIXADI.

How long will I be on BRIXADI?

OUD is a chronic, relapsing disease, which means that long-term treatment (including medicine and counseling) may be needed. Your healthcare provider will decide how long you should stay on medicine. Talk to your healthcare provider about your treatment goals.



Scan the QR code for answers to more [commonly asked questions](#).

Important Safety Information (Continued)

What are the possible side effects of BRIXADI? (continued)

- **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.

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How do I get my prescription?

After I am prescribed BRIXADI, what do I need to do to ensure that my prescription is filled in a timely fashion?

Your healthcare provider may get BRIXADI for you through a specialty pharmacy. A specialty pharmacy is different from a local retail pharmacy. After your healthcare provider prescribes BRIXADI, you may get a call or text message from a specialty pharmacy. However, if your healthcare provider does not get BRIXADI for you through a specialty pharmacy, you will not get a call or text.



Be sure to **answer the call or text**, or the medicine may not be delivered on time to your healthcare provider's office.



Remember to write down the name and phone number of the specialty pharmacy that received your BRIXADI prescription:

Name of specialty pharmacy:

Phone number of specialty pharmacy:

Important Safety Information (Continued)

What are the possible side effects of BRIXADI? (continued)

- **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.

Can I get help paying for BRIXADI?

You may be eligible* to pay as little as

\$0 per injection

If you have private insurance, you may be eligible* to pay as little as \$0 per injection through the BRIXADI Copay Savings Program. Copay savings reset at the beginning of each calendar year.



Scan the QR code to get guidance on how to enroll in the [BRIXADI Copay Savings Program](#).

*Patients are not eligible for copay savings if they participate in a federal or state healthcare program, including, but not limited to, Medicaid, Medicare, Veterans Affairs (VA), Department of Defense (DoD), TRICARE, or other federal and state patient or pharmaceutical assistance program. Void where prohibited by law. Program terms and conditions apply.

- **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.

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- 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.

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.
- **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.

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Important Safety Information (Continued)

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
 - 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.

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Key points to remember



OUD is a chronic, relapsing disease that can be managed like other chronic diseases.



BRIXADI is a medicine used along with counseling to treat moderate to severe OUD.



BRIXADI is available in a once-a-week or once-a-month dose that can help reduce opioid use.



Talk to your healthcare provider about starting or switching to BRIXADI.

Important Safety Information (Continued)

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.**
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Plymouth Meeting, PA 19462

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