# PREPARING FOR A Visit with your healthcare provider

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

Throughout your treatment journey, it's important to work with your healthcare provider. Working together can help you fully understand your prescribed medications and your treatment plan. Use this guide to plan for your visit and know what questions to ask about starting and staying on BRIXADI.

# **Questions about BRIXADI and how it works:**

- What is BRIXADI?
- Why has BRIXADI been prescribed to me?
- How does BRIXADI work?
- How well does BRIXADI work compared to oral buprenorphine?
- How soon will BRIXADI start working?
- Will I experience any cravings or withdrawal symptoms?

# Questions about starting and staying on BRIXADI:

- How will I receive BRIXADI?
- Where do I go to get my BRIXADI injection, and how do I schedule it?
- Will I need to pick up my prescription at a pharmacy?
- What is the injection process like?
  - Where on my body will the injection be given?
  - Who will give me my injection?
  - Will the injection be painful?

- Which is best for me, the once-a-week or once-a-month dosing option?
  - Will I be able to change from one dosing option to the other once I start?
- What should I avoid doing while receiving BRIXADI?
- What are the possible side effects?
- Can I safely take my other medications while on BRIXADI?
- Can I take BRIXADI if I'm pregnant or breastfeeding?
- How long will I be on BRIXADI?
- What happens if I can't have my next injection in exactly 1 week or 1 month?
- What do I do if I miss a dose of BRIXADI?
- What happens if I stop taking BRIXADI?
- Can I get help paying for BRIXADI?

Use the space below to write down more questions you may have:

Use the space below to write down notes from your visit:

## INDICATION

#### 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.

It is not known if BRIXADI is safe and effective in children

## Please see Important Safety Information on the following pages.

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



### **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 controlled 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 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. Call your healthcare provider right away or get emergency help if you:
  - feel faint or dizzy
  - · have mental changes such as confusion
  - · have slower breathing than you normally have
  - have severe sleepiness
  - have blurred vision
  - · have problems with coordination

- cannot think well or clearly
- have a high body temperature
- have slowed reflexes
- · feel agitated
- have stiff muscles
- · have trouble walking

have slurred speech

These can be signs of an overdose or other serious problems.

- 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.
- Death or serious harm can happen if you take anxiety medicines or benzodiazepines, sleeping pills, tranquilizers, muscle relaxants, or sedatives, antidepressants, or antihistamines, or drink alcohol during treatment with BRIXADI. Tell your healthcare provider if you are taking any of these medicines and if you drink alcohol.
- In an emergency, you or your family should tell the emergency medical staff that you are physically dependent on an opioid and are being treated with BRIXADI.

BRIXADI is a controlled substance (CIII) because it contains buprenorphine that can be a target for people who abuse prescription medicines or street drugs.

**Do not use BRIXADI** if you are allergic to buprenorphine or any other ingredients in BRIXADI (soybean phosphatidylcholine, glycerol dioleate, anhydrous ethanol [only BRIXADI (weekly)], *N*-methyl-2-pyrrolidone (NMP) [only BRIXADI (monthly)]).

# BRIXADI may not be right for you. Before starting BRIXADI, tell your healthcare provider about all of your medical conditions, including:

- Trouble breathing or lung problems
- QTc prolongation or a family history of it
- An enlarged prostate gland (men)
- A head injury or brain problem
- Problems urinating
- A curve in your spine that affects your breathing (scoliosis)
- Liver problems
- Gallbladder problems
- Adrenal gland problems
- Addison's disease

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## **IMPORTANT SAFETY INFORMATION (CONTINUED)**

- Low thyroid hormone levels (hypothyroidism)
- A history of alcoholism
- Mental problems such as hallucinations (seeing or hearing things that are not there).
- A latex allergy. The BRIXADI needle cap contains latex.
- 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 plan to become pregnant.
- Are breastfeeding or plan to breastfeed. BRIXADI can pass into your breast milk and may harm your baby. Talk with your healthcare provider about the best way to feed your baby during treatment with BRIXADI. Monitor your baby for increased drowsiness and breathing problems.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. BRIXADI may affect the way other medicines work and other medicines may affect how BRIXADI works. Some medicines may cause serious or life-threatening medical problems when taken with BRIXADI. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist each time you get a new medicine.

- The doses of certain medicines may need to be changed if used during treatment with BRIXADI. Do not take any medicine during treatment with BRIXADI until you have talked with your healthcare provider. Your healthcare provider will tell you if it is safe to take other medicines during treatment with BRIXADI.
- You should not take anxiety medicines or benzodiazepines, sleeping pills, tranquilizers, muscle relaxants, or sedatives, antidepressants, or antihistamines that are not prescribed to you during treatment with BRIXADI, as this can lead to slowed breathing, drowsiness, delayed reaction time, loss of consciousness or even death. If a healthcare provider is considering prescribing such a medicine for you, remind the healthcare provider that you are being treated with BRIXADI.
- You may have detectable levels of BRIXADI in your body for several months after stopping treatment with BRIXADI.

#### What should I avoid while being treated with BRIXADI?

- Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how this medicine affects you. Buprenorphine can cause drowsiness and slow reaction times. This may happen more often in the first day after your injection and when your dose is being changed.
- You should not drink alcohol or use 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:

- **Physical dependence and withdrawal.** Your body can develop a physical need (dependence) for BRIXADI. If you stop receiving BRIXADI, you could have opioid withdrawal symptoms such as:
  - shaking, goose bumps, muscle aches
  - sweating more than normal
  - feeling hot or cold more than normal

- runny nose and watery eyes
- diarrhea or vomiting
- These symptoms may start weeks to months after your last dose of BRIXADI. Tell your healthcare provider if you develop any of these symptoms.
- Liver problems. Call your healthcare provider right away if you notice any of these signs of liver problems:
- your skin or the white part of your eyes turns yellow (jaundice)
- decreased appetite
- stomach (abdomen) pain or nausea

- urine turns dark
- · bowel movements (stools) turn light in color

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

#### Please see additional Important Safety Information on the following page.

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## **IMPORTANT SAFETY INFORMATION (CONTINUED)**

- Allergic reaction. Call your healthcare provider or get emergency help right away if you get:
  - rash, hives, itching
  - swelling of your face

- wheezing
- dizziness, or a decrease in consciousness
- Heart problems. BRIXADI can cause a heart problem called QTc prolongation. QTc prolongation causes an irregular heartbeat. Your healthcare provider should check the electrical activity of your heart with a test called an electrocardiogram (ECG) during treatment with BRIXADI.
- Decrease in blood pressure. You may feel dizzy when you get up 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)
- urinary tract infection
- Long-term chronic use of opioids, including BRIXADI, may cause fertility problems 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 <u>www.fda.gov/medwatch</u> or call 1-800-FDA-1088.

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

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

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