INSTRUCTIONS FOR USE BOOKLET

(buprenorphine) extended-release injection for subcutaneous use CIII

Weekly 8 • 16 • 24 • 32 mg **Monthly** 64 • 96 • 128 mg

WELCOME

This guide contains information on the appropriate use of BRIXADI® (buprenorphine) extended-release injection for subcutaneous use, which is a single-dose, sterile pre-filled syringe for the treatment of moderate-to-severe opioid use disorder.

Prior to injecting BRIXADI, carefully read these instructions as well as the full Prescribing Information.

As a universal precaution, always wear gloves and inject BRIXADI under aseptic conditions.

INDICATIONS AND USAGE

BRIXADI is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine.

BRIXADI should be used as part of a complete treatment plan that includes counseling and psychosocial support.

DOSAGE FORMS AND STRENGTHS

FOR SUBCUTANEOUS INJECTION ONLY. DO NOT ADMINISTER BRIXADI INTRAVENOUSLY, INTRAMUSCULARLY, OR INTRADERMALLY.

- BRIXADI exists in two formulations.

DOSAGE FORMS AND STRENGTHS (continued)

- Doses of BRIXADI (weekly) cannot be combined to yield a monthly dose.
- Only healthcare providers should prepare and administer BRIXADI.
- Administer BRIXADI as a single injection. Do not divide.
- BRIXADI should be injected slowly, into the subcutaneous tissue of the buttock, thigh, abdomen, or upper arm.
  - In patients who are not currently receiving buprenorphine treatment, for BRIXADI (weekly), the upper arm site should only be used after steady state has been achieved (4 consecutive doses). Injection in the arm site was associated with approximately 10% lower plasma levels than other sites.
- Injection sites should be alternated/rotated between injections for BRIXADI (weekly).
- For all patients, the dose of BRIXADI must be individualized based on patient tolerability and/or efficacy.
- BRIXADI (weekly) should be administered in 7-day intervals.

DOSAGE FORMS AND STRENGTHS (continued)

- BRIXADI (monthly) should be administered in 28-day intervals.
- For patients not currently receiving buprenorphine treatment, begin with a test dose of 4 mg transmucosal buprenorphine to establish that buprenorphine is tolerated without precipitated withdrawal, and then transition to BRIXADI (weekly). Initiating treatment with BRIXADI as the first buprenorphine product has not been studied. Initiating treatment with BRIXADI (monthly) in new entrants to treatment has not been studied.
- Patients who are currently being treated with other buprenorphine-containing products can start treatment with either BRIXADI (weekly) or BRIXADI (monthly).
- Administer each injection using only the syringe and safety needle included with the product. Caution: The BRIXADI needle cap is synthetically derived from natural rubber latex which may cause allergic reactions in latex-sensitive individuals.
- BRIXADI (weekly) is available in: 8 mg, 16 mg, 24 mg, and 32 mg.
- BRIXADI (monthly) is available in: 64 mg, 96 mg, and 128 mg.

DOSAGE FORMS AND STRENGTHS (continued)

To avoid missed doses, the weekly dose may be administered up to 2 days before or after the weekly time point, and the monthly dose may be administered up to 1 week before or after the monthly time point.

If a dose is missed, the next dose should be administered as soon as practically possible.

INSTRUCTIONS FOR SAFETY SYRINGE USE

- Always use the injection technique described in the Instructions for Use.
- Do not use if the safety syringe is broken, or if the packaging is damaged.
- Do not uncap the safety syringe until you are ready to inject. Once it is uncapped, never try to recap the needle.
- Do not re-use the safety syringe.
- Examine the contents of the safety syringe carefully through the transparent housing. The liquid should be clear and yellowish to yellow in color. Inspect for cracks or breakage in the syringe or other parts. Do not use if the syringe is cracked or broken, or if the liquid is cloudy, discolored, or contains particles.

CONTRAINDICATIONS

- BRIXADI is contraindicated in patients with hypersensitivity (e.g., anaphylactic shock) to buprenorphine, or any other ingredients in the solution for injection.

ADDITIONAL IMPORTANT INFORMATION

- Store BRIXADI in its original packaging until ready for use.
- Check the expiration date on the BRIXADI label and its carton. If the medication has expired, do not use it.
- Injecting BRIXADI may cause skin reactions including redness, pain, or itching. Patients should be instructed to contact their healthcare provider if skin reactions occur.
- Do not inject BRIXADI where the skin is irritated, reddened, bruised, infected, or abnormal in any way.

HOW SUPPLIED AND STORAGE

- BRIXADI is individually packaged. Each carton contains one safety syringe and one plunger. The parts of the syringe are outlined in **Figures 1, 2, and 3**.
- BRIXADI should be stored at room temperature at 20°C to 25°C (68°F to 77°F); with excursions permitted at 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].
- BRIXADI is a Schedule III drug product. Handle with adequate security and accountability. After administration, syringes should be properly disposed per facility procedure for a Schedule III drug product, and per applicable federal, state, and local regulations.

SAFETY SYRINGE PARTS
(see Figures 1, 2, 3 below)

Figure 1

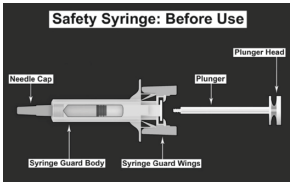


Figure 2

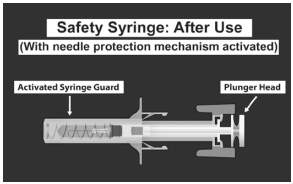
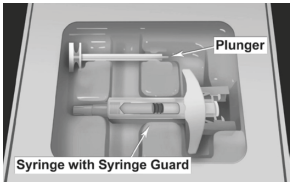


Figure 3



MATERIALS NEEDED FOR INJECTION:

Illustrated in Figure 4.

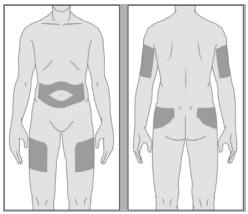
- Alcohol wipe
- Cotton ball
- Sharps disposal container

Figure 4

SELECTING AN INJECTION SITE

The areas for subcutaneous injection are highlighted in **Figure 5**. **BRIXADI should not be administered to the same site of injection for at least 8 weeks for BRIXADI (weekly). No injection site rotation is required for BRIXADI (monthly).**

Figure 5



BRIXADI should be injected slowly into the subcutaneous tissue of the buttock, thigh, abdomen, or upper arm.

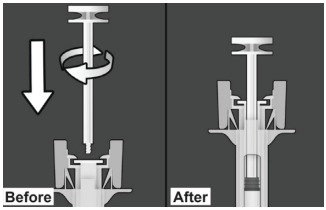
In patients who are not currently receiving buprenorphine treatment, for BRIXADI (weekly), the upper arm site should only be used after steady-state has been achieved (4 consecutive doses).

PREPARE THE SAFETY SYRINGE

Step 1:
Wash hands thoroughly with soap and water prior to handling the safety syringe.

Step 2:
Remove the safety syringe components from the carton. Assemble the safety syringe. While holding the syringe guard body, insert the plunger into the body of the syringe and rotate clockwise until it is attached to the stopper inside the syringe as illustrated in **Figure 6**.

Figure 6



Step 3:
Inspect the safety syringe closely:

Do not use the safety syringe after the expiration date shown on the carton or on the safety syringe label.

- The liquid should be clear and yellowish to yellow in color.
- A small air bubble may be visible.

Do not use the safety syringe if the liquid contains visible particles or is cloudy.

PREPARATION OF SITE

Step 4:

- Put on gloves.
- Clean the injection site with an alcohol wipe using a circular motion.

Do not touch the cleaned area again before injecting.

ADMINISTERING INJECTION

Step 5:

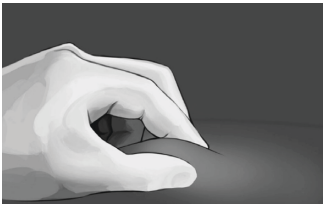
- Grasp the safety syringe by the syringe, as shown **(see Figure 7)**.
- Carefully pull the needle cap straight off.
- Immediately dispose of the needle cap (Never try to recap the needle).

It is normal to see a small drop of liquid at the tip of the needle.

Figure 7

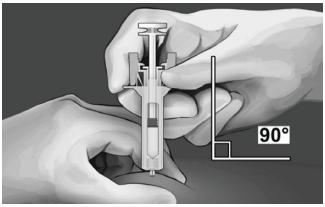
Step 6:
Pinch the skin at the injection site between your thumb and index finger as shown in **Figure 8**.

Figure 8



Step 7:
Hold the syringe, as shown, and insert the needle at an angle of approximately 90° **(see Figure 9)**. The needle is designed to inject into the subcutaneous space. It is important to fully insert the needle.

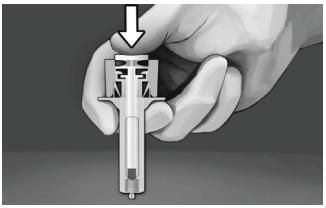
Figure 9



Step 8:

- After the needle is completely inserted into the subcutaneous tissue, release the skin that you are grasping. Slowly press down the plunger head until it latches in the safety device 'wings' **(see Figure 10)**. This will ensure that all of the medication has been injected.

Figure 10

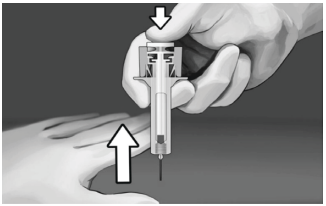


- **Keep the plunger pressed fully down while you hold the safety syringe in place for an additional 2 seconds.**

Step 9:

- Gently pull the needle out of the skin.
- Keep the plunger fully depressed while you carefully lift the needle straight out from the injection site **(see Figure 11)**.

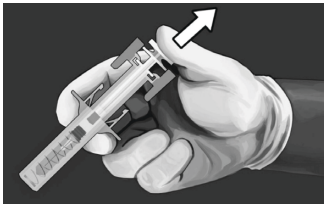
Figure 11



Step 10:

- As soon as you have completely removed the needle from the skin, slowly take your thumb off the plunger.
- Allow the syringe guard to automatically cover the exposed needle **(see Figure 12)**.
- There may be a small amount of blood at the injection site. If needed, wipe with a cotton ball or gauze.

Figure 12

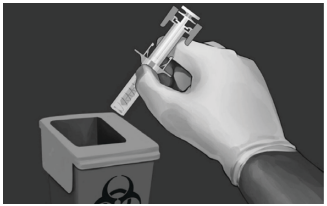


DISPOSAL OF USED SAFETY SYRINGE

Step 11:

Put the used safety syringe immediately into a sharps container **(see Figure 13)**.

Figure 13



POST INJECTION CARE

- Examine the injection site.
- If there is blood, press a cotton ball or gauze pad on the injection site.
- Do not rub the injection site.
- Apply an adhesive bandage if needed.
- Patient should be instructed to notify you immediately if excessive swelling, redness, heat, or drainage develops at the injection site.

Scan or click here to view a video on How to Administer BRIXADI®

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