



ECHO IDAHO: Opioids, Pain & Substance Use Disorders

Long-Acting Injectable Buprenorphine 08/08/24
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Learning Objectives







IDENTIFY CANDIDATES FOR LONG-ACTING INJECTABLE BUPRENORPHINE COUNSEL PATIENTS ON PROS AND CONS OF INJECTABLE BUPRENORPHINE

COMPARE INJECTION
CHARACTERISTICS BETWEEN
BRIXADI AND SUBLOCADE

Sublingual Buprenorphine Formulations for OUD

Monoproduct tabs



Combo product tabs



Combo product films















- Brixadi and Sublocade
- REMS medications
- Subcutaneous
- Crystalline matrix
- Open formulary VA and Medicaid
- Risks same as transmucosal buprenorphine + local skin reactions (and – dental concerns)

Patient Selection

Indications

- Concern for diversion
- Intermittent treatment adherence
- Justice involvement
- Medication storage concerns
- Patient preference
- Dental concerns?

Contraindications

- Allergy to components
- Upcoming major surgery
- Moderate/severe hepatic impairment
- Cellulitis/scarring at site



Brixadi

 Prior to start: 4mg SL x1 (weekly) or "stable" dose of SL buprenorphine (monthly)

• Needle: 23-gauge

• Volume: 0.16mL-0.64mL

Surgical removal: No

• Notes: decreased absorption in arms



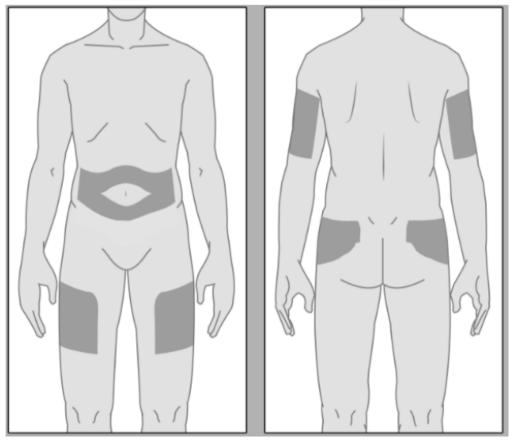
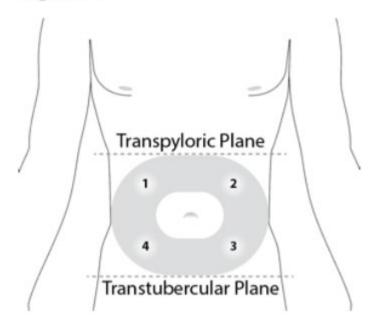






Figure 4



Sublocade

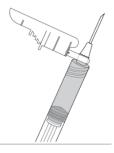


• Needle: 18 gauge,

• Volume: 0.5mL (100mg) or 1.5mL (300mg)

• Surgical excision: first 14 days

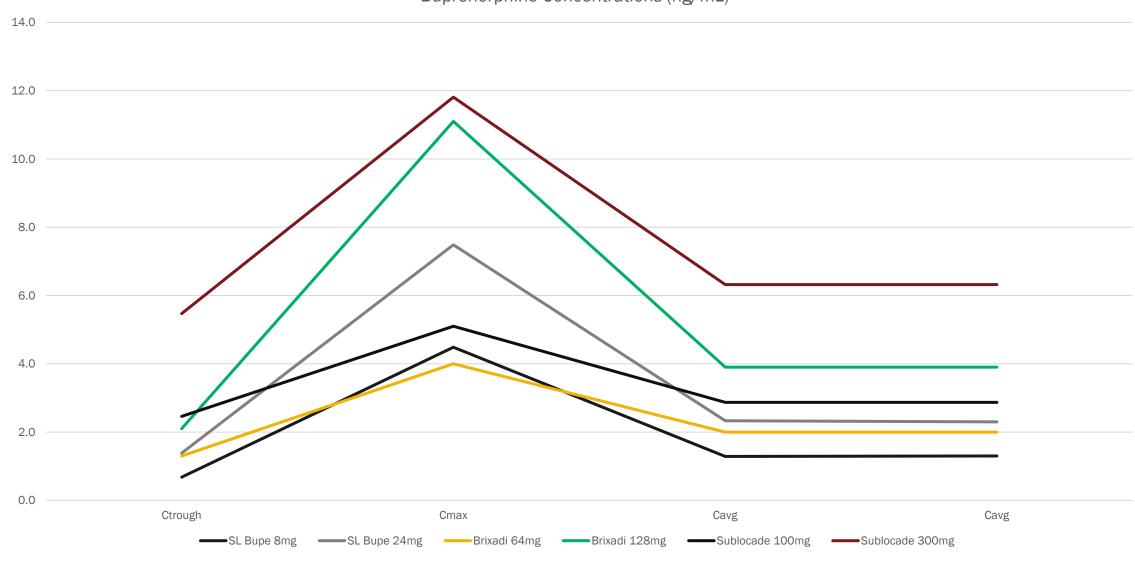
• Notes: stings, starting regimen





Sublingual Buprenorphine*	Brixadi (weekly)	Brixadi (monthly)	Sublocade (dose 1)	Sublocade (dose 2)	Sublocade (maintenance)
<6mg	8mg	n/a	n/a		
8-10mg	16mg	64mg	300mg	100mg	100mg
12-16mg	24mg	96mg	300mg	100mg*	100mg
18-24mg	32mg	128mg	300mg	300mg	100mg
>24mg			300mg	300mg	300mg





REMS

- No certification to prescribe
- Meds can be obtained from REMS-certified pharmacy for individual patients at a specified appt time without REMS certification
- REMS required to stock Sublocade and Brixadi

FDA-REQUIRED REMS SAFETY INFORMATION

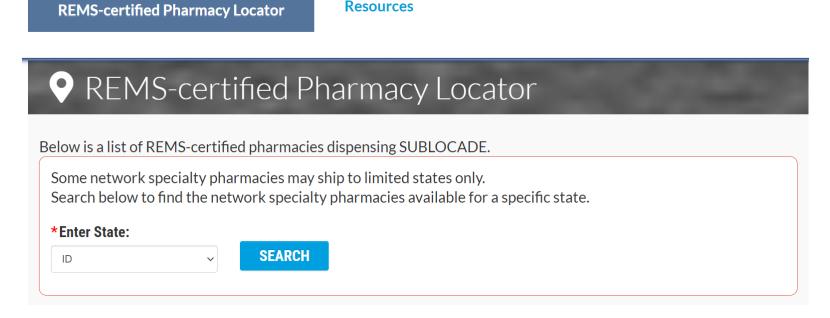
WARNING: RISK OF SERIOUS HARM OR DEATH WITH INTRAVENOUS ADMINISTRATION; SUBLOCADE RISK EVALUATION AND MITIGATION STRATEGY

- Serious harm or death could result if administered intravenously. SUBLOCADE forms a solid mass upon contact with body fluids and may cause occlusion, local tissue damage, and thrombo-embolic events, including life threatening pulmonary emboli, if administered intravenously.
- Because of the risk of serious harm or death that could result from intravenous self-administration, SUBLOCADE is only available through a restricted program called the SUBLOCADE REMS. Healthcare settings and pharmacies that order and dispense SUBLOCADE must be certified in this program and comply with the REMS requirements.

Start prescribing/dispensing

The BRIXADI REMS Fact Sheet is enclosed, or you can also access it by visiting www.BrixadiRems.com/Fact-Sheet or scanning the QR code below:









Key Points

Injectable buprenorphine is a great option for select patients

Risks associated with use <<< untreated opioid use disorder

Brixadi has more dosing options; Sublocade achieves higher serum levels

References

- Brixadi package insert updated 5/2023
- Sublocade package insert revised 12/2023



Table 7: Summary of steady-state PK parameters of buprenorphine after subcutaneous buttock injections of BRIXADI (weekly) and BRIXADI (monthly) and sublingual (SL) administration of SUBUTEX

Drug product dose		Cav (ng/mL)			C _{max} (ng/mL)			C _{trough} ^a (ng/mL)			
SL BPN	Brixadi (weekly)	Brixadi (monthly)	SL BPN	Brixadi (weekly)	Brixadi (monthly)	SL BPN	Brixadi (weekly)	Brixadi (monthly)	SL BPN	Brixadi (weekly)	Brixadi (monthly)
			*			*			*		
8 mg	16 mg	64 mg	1.2	2.1	2.0 \$	4.7	4.3	4.0 \$	0.7	0.8	1.3 \$
16 mg	24 mg	96 mg	1.8	2.9 \$	2.9 \$	6.5	5.5 ^{\$}	6.0 \$	1.0	1.4 \$	2.0 \$
24 mg	32 mg	128 mg	2.5	4.2	3.9	8.2	6.9	11.1	1.4	2.6	2.1

Table 7 Comparison of Steady-state Buprenorphine Plasma Exposure Between Daily Transmucosal Buprenorphine and Once Monthly SUBLOCADE at Trough (Ctrough), Average (Cavg) and Peak (Cmax) Levels (Geometric Mean (CV%))

Pharmacokinetic	T	ransmucosal E	SUBLOCADE			
parameters	8 mg	12 mg	16 mg	24 mg	100 mg	300 mg
C _{avg,ss} (ng/mL)	1.37	1.79	2.16	2.84	2.87	6.32
	(40)	(40)	(40)	(40)	(32)	(32)
C _{max,ss} (ng/mL)	4.27	5.60	6.77	8.86	5.10	11.81
	(45)	(45)	(45)	(45)	(33)	(35)
C _{trough,ss} (ng/mL)	0.66	0.87	1.04	1.37	2.46	5.47
	(63)	(63)	(61)	(62)	(40)	(39)



