MEDICATION ASSISTED TREATMENT FOR OPIOID USE DISORDER, PART 1

OPIOIDS, ADDICTION AND PAIN ECHO
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PHARMACOLOGICAL TREATMENT OF ADDICTION

- Treat overdose

- Facilitate abstinence
  - Medically-supervised withdrawal ("detoxification")
  - Restore balance to brain systems
  - Treat co-occurring conditions

- Prevent relapse
  - Reduce stress
  - Address cues/craving
  - Support healthier cognitive function/decision-making
  - Block action of drugs

U.S. FDA-APPROVED MEDICATIONS FOR ADDICTION TREATMENT (LAST NEW ONE 2004)

Medication	Indication(s)
Disulfiram (Antabuse®)	Alcohol dependence
Nicotine replacement therapies	Nicotine dependence
Bupropion (Wellbutrin®, Zyban®)	Nicotine dependence
Varenicline (Chantix®)	Nicotine dependence
Naltrexone (ReVia®, Vivitrol®)	Alcohol dependence Opioid dependence
Acamprosate (Campral®)	Alcohol dependence
Methadone	Opioid dependence/withdrawal
Buprenorphine (Subutex®, others)	Opioid dependence/withdrawal
Buprenorphine-naloxone (Suboxone®, others)	Opioid dependence/withdrawal

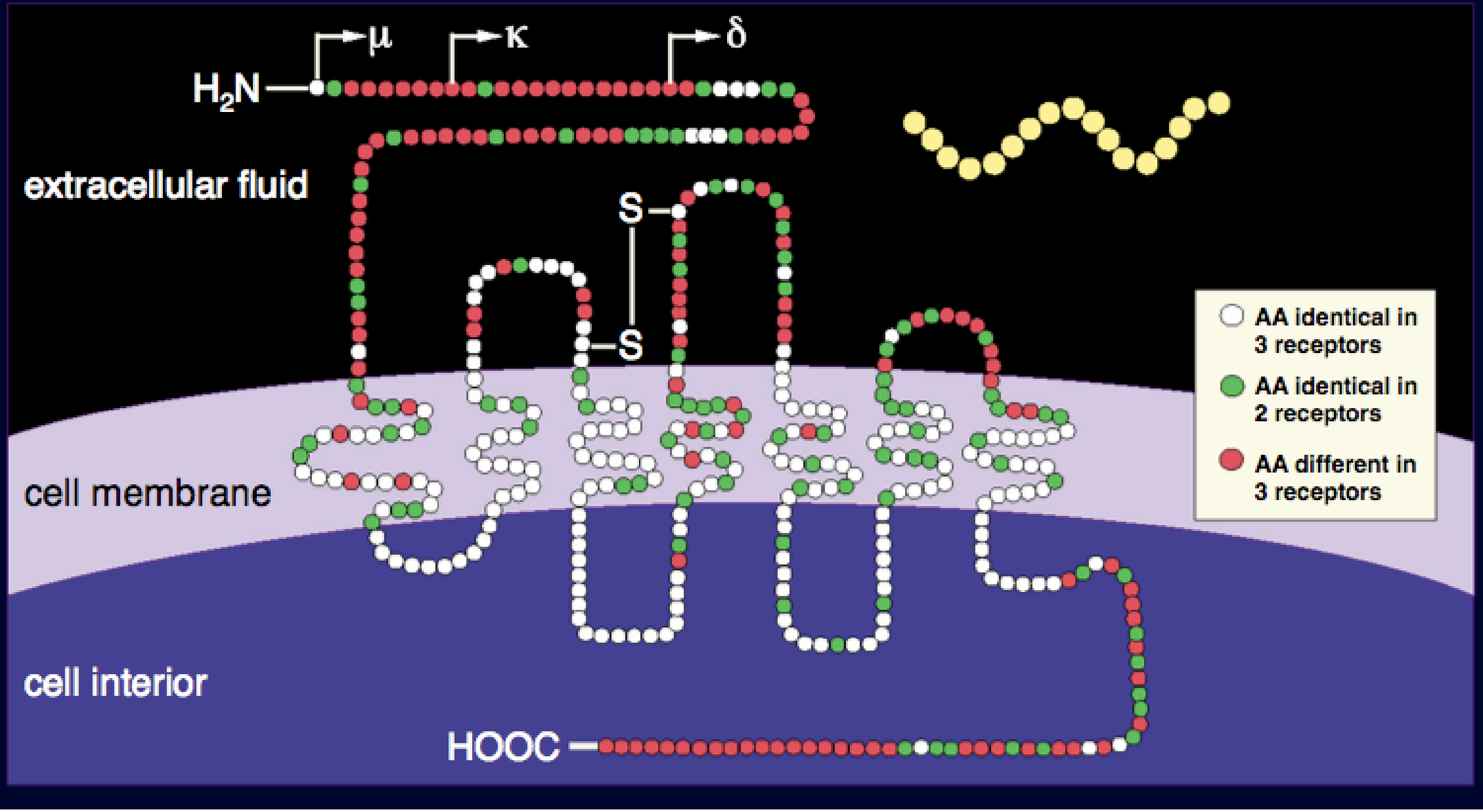
NICOTINE

OPIOIDS

OPIATES, OPIOIDS

Opiates	Semi-Synthetic Opioids	Synthetic Opioids	Endogenous Opioids
Naturally occur in resin of opium poppy	**Synthesized from naturally-occurring opiates**	**Synthesized entirely from non-opiate components**	**Naturally occur in the brain/CNS**
Opium (Paregoric, etc)	Diacetylmorphine (Heroin)	Propoxyphene (off market 2010)	Endorphins
Morphine (MS-Contin, etc.)	Oxycodone (Oxycontin, Roxicodone, etc.)	Fentanyl (Duragesic, Actiq)	Enkephalins
Codeine (Tylenol #3, etc.)	Hydrocodone (Lortab, Vicodin, etc.)	Methadone (Dolophine)	Dynorphin
Papaverine	Hydromorphone (Dilaudid)	Meperidine (Demerol)	Others
Thebaine (parent of buprenorphine)	Buprenorphine (Suboxone, Subutex)	Tramadol (Ultram)	
Noscapine			

Human Opioid Receptors μ, δ, and κ



LaForge, Yuferov and Kreek, 2000: https://doi.org/10.1016/S0014-2999(00)00819-0

OPIOID RECEPTOR ACTIVITY

Opioid	Mu receptor	Kappa receptor	Delta receptor	ORL-1/ NOP
Morphine	Agonist	Agonist	Agonist	
Nalorphine	Antagonist	Partial agonist	Partial agonist	
Pentazocine	Antagonist	Agonist	Partial agonist	
Nalbuphine	Antagonist	Agonist	Agonist	
Buprenorphine	Partial agonist	Antagonist/ Partial agonist	Antagonist	Partial agonist
Butorphanol	Antagonist	Agonist	Agonist	
Naloxone/ Naltrexone	Antagonist	Antagonist	Antagonist	
Nalmefene	Antagonist			

MEDICATIONS FOR OPIOID USE DISORDERS, MECHANISMS OF ACTION

- Naltrexone
  - Oral tablets, Depot injectable
  - Mu opioid receptor blockade
- Buprenorphine
  - Sublingual tablets, film; buccal film
  - Long-acting implantable rods
  - Mu opioid receptor partial agonist
- Methadone
  - Tablets, liquid
  - Mu opioid receptor full agonist

Exhibit 1: Key Differences Between Medications Used To Treat Patients With Opioid Dependence

Prescribing Considerations	Extended-Release Injectable Naltrexone	Buprenorphine	Methadone
Frequency of Administration	Monthly	Daily	Daily
Route of Administration	Intramuscular injection in the gluteal muscle by healthcare professional.	Oral tablet or film is dissolved under the tongue. Can be taken at a physician's office or at home.	Oral (liquid) consumption usually witnessed at an OTP, until the patient receives take-home doses.
Restrictions on Prescribing or Dispensing	Any individual who is licensed to prescribe medicine (e.g., physician, physician assistant, nurse practitioner) may prescribe and order administration by qualified staff.	Only licensed physicians who are DEA registered and either work at an OTP or have obtained a waiver to prescribe buprenorphine may do so.	Only licensed physicians who are DEA registered and who work at an OTP can order methadone for dispensing at the OTP.
Abuse and Diversion Potential	No	Yes	Yes
Additional Requirements	None; any pharmacy can fill the prescription.	Physicians must complete limited special training to qualify for the DEA prescribing waiver. Any pharmacy can fill the prescription.	For opioid dependence treatment purposes, methadone can only be purchased by and dispensed at certified OTPs or hospitals.

Sources: Adapted from [16, 18, 19]

OPIOID ADDICTION TREATMENT OUTCOMES

Treatment	Outcome*
Methadone Maintenance	50 – 80%
Buprenorphine-Naloxone Maintenance	40 – 50%**
Naltrexone Maintenance (oral or depot)	10 – 20%
“Drug-free” (Non-pharmacotherapeutic)	5 – 20%
Short-term Detoxification (any mode)	5 – 20%

* One year retention in treatment and/or follow-up with significant reduction or elimination of illicit use of opiates

** Maximum effective dose (24mg SL) equal to 60 to 70 mg/day methadone. Data based on 6 month follow-up only.

Kreek, 1996; 2001; 2003; 2016

BUPRENORPHINE FOR OPIOID USE DISORDERS

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PRESCRIBING OF BUPRENORPHINE IN U.S.

- **Drug Abuse Treatment Act (DATA 2000):**
  - Allowed opioid detoxification and primary addiction treatment in the office-based setting with Schedules III, IV or V agents approved for addiction treatment
  - Physicians must qualify and register for a special DEA number if using buprenorphine-naloxone or buprenorphine for addiction treatment (XA#######)
  - [Initial law] ONLY physicians can prescribe for addiction treatment with 30 patient limit per physician after special training
  - Later revisions allowed:
    - increase patient limit to 100-275 after one year, depending on qualifications
    - addition of PA's and APRN's to prescribe
- Approval of sublingual buprenorphine for the treatment of opioid addiction is significant
  - First time (since a U.S. Supreme Court ruling in 1918) that physicians [and other prescribers] have been allowed to manage opioid addiction in the office-based setting
  - Shift to medical management model

https://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management; http://pcssnow.org

BUPRENORPHINE

- Semi-synthetic opioid derived from thebaine (naturally occurring alkaloid of opium poppy)
- 25-40 times more potent than morphine
  - 1 mg buprenorphine==25-40 mg morphine
- Extensive first-pass metabolism
- Very low oral bioavailability
  - Minimally absorbed if swallowed (except in kids)
  - Sublingual bioavailability adequate
- T_{max} (Mean time to maximum plasma concentration)==40 minutes to 3.5 hours
- Elimination half-life=37 hours (3-44 hours)

BUPRENORPHINE AND THE CYTOCHROME P450 3A4 SYSTEM

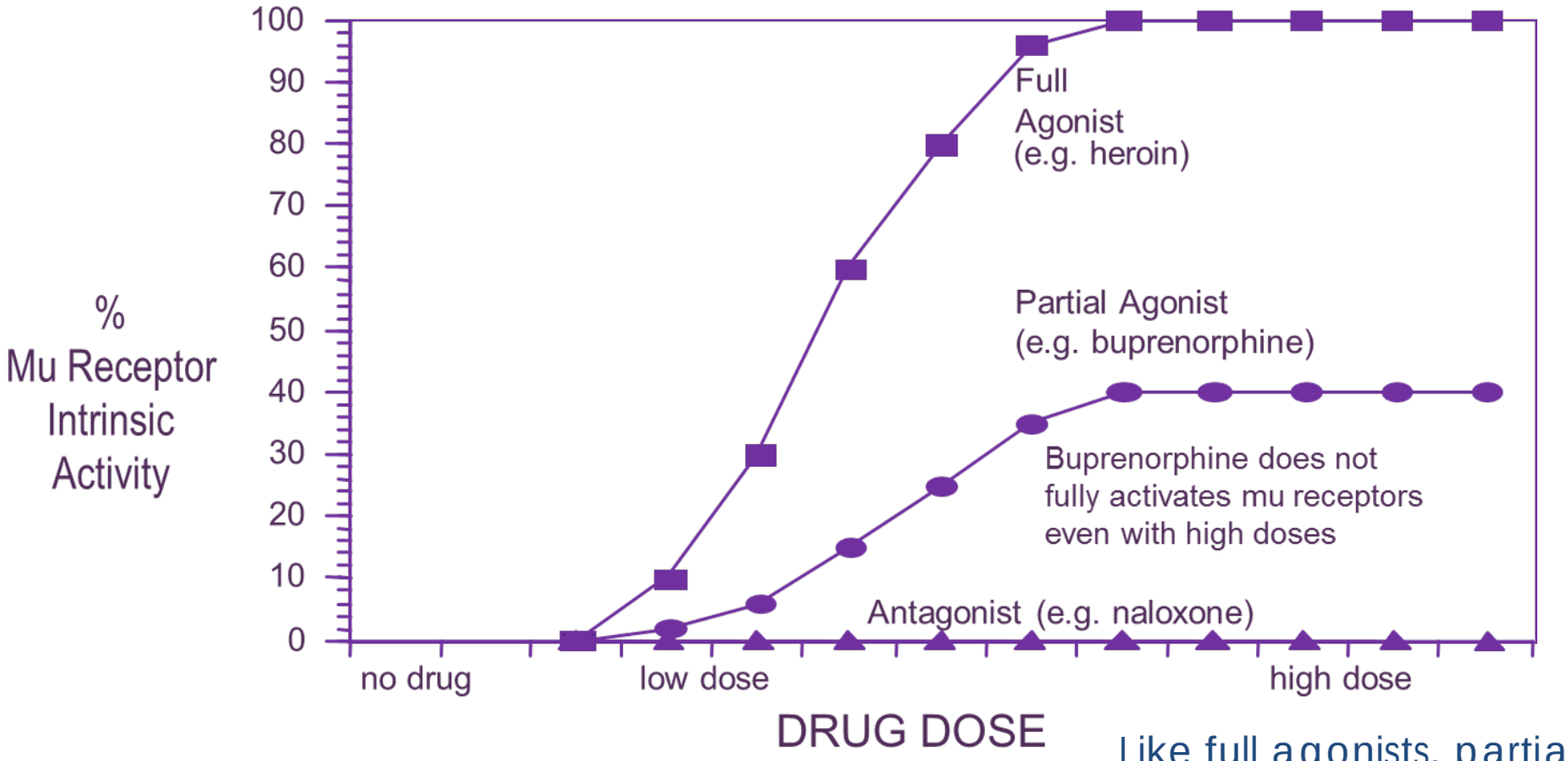
3A4 Inhibitors May Raise Bup Levels	3A4 Substrates: May Raise Bup Levels	3A4 Inducers: May Lower Bup Levels
Fluoxetine	Trazodone	Carbamazepine
Fluvoxamine	Alprazolam	Phenobarbital
Nefazodone	Diazepam	Phenytoin
Cimetidine	Buspirone	Barbiturates
Delavirdine	Zolpidem	Primidone
	Caffeine	St John's Wort
	Haloperidol	Rifampin
	Pimozide	Efavirenz
	Erythromycin	Nevirapine
	Nifedipine	
	Oral contraceptives	

BUPRENORPHINE PHARMACOLOGY

- Partial Mu opioid receptor agonist
  - Ceiling effect for respiratory depression-clinically
  - Safer in overdose
  - High affinity for Mu opioid receptor
- Non-selective Kappa opioid receptor antagonist/partial agonist
  - ?Antidepressant effects?
  - ?Antianxiety effects?
- ORL-1 receptor partial agonist
  - Less hyperalgesia?
- Metabolite norbuprenorphine
  - N-dealkylated metabolite
  - Does not contribute to respiratory depression

PARTIAL AND FULL OPIOID AGONIST ACTIVITY

At higher doses, even when partial agonist drug completely binds all mu receptors, maximum opioid agonist effect is never achieved



Like full agonists, partial agonist drugs produce increasing mu opioid receptor specific activity at lower doses

INDUCTION WITH BUPRENORPHINE

- Clinical Opioid Withdrawal Scale (COWS) score should be in the moderate withdrawal range (13-24; some dose at lower scores) before starting buprenorphine, to avoid precipitated withdrawal
- Estimated time after last dose before starting Bup:
  - Heroin, other short-acting opioids: 12-36 hours
  - Fentanyl patches, Oxycodone/others SR: 36-72 hours
  - Methadone: 48-72 hours

CLINICAL OPIOID WITHDRAWAL SCALE (COWS)

Clinical Opiate Withdrawal Scale (COWS)

For each item, circle the number that best describes the patient's signs or symptoms. Rate just on the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increased pulse rate would not add to the score.

Patient Name: _____	**Date:** _____	**Time:** _____
Reason for this assessment:		

1. Resting pulse rate: _____ beats/minute *Measured after the patient is sitting or lying for one minute.*	**7. GI upset:** *over last half hour*
0 Pulse rate 80 or below	0 No GI symptoms
1 Pulse rate 81-100	1 Stomach cramps
2 Pulse rate 101-120	2 Nausea or loose stool
4 Pulse rate greater than 120	3 Vomiting or diarrhea
	5 Multiple episodes of diarrhea or vomiting
2. Sweating: *over past half hour not accounted for by room temperature of patient activity*	**8. Tremor:** *observation of outstretched hands*
0 No reports of chills or flushing	0 No tremor
1 Subjective reports of chills or flushing	1 Tremor can be felt, but not observed
2 Flushed or observable moisture on face	2 Slight tremor observable
3 Beads of sweat on brow or face	4 Gross tremor or muscle twitching
4 Sweat streaming off face	
3. Restlessness: *observation during assessment*	**9. Yawning:** *observation during assessment*
0 Able to sit still	0 No yawning
1 Reports difficulty sitting still, but is able to do so	1 Yawning once or twice during assessment
3 Frequent shifting or extraneous movements of legs/arms	2 Yawning three or more times during assessment
5 Unable to sit still for more than a few seconds	4 Yawning several times/minute
4. Pupil size	**10. Anxiety or irritability**
0 Pupils pinned or normal size for room light	0 None
1 Pupils possibly larger than normal for room light	1 Patient reports increasing irritability or anxiousness
2 Pupils moderately dilated	2 Patient obviously irritable, anxious
5 Pupils so dilated that only the rim of the iris is visible	4 Patient so irritable or anxious that participation in the assessment is difficult
5. Bone or joint aches: *if patient was having pain previously, only the additional component attributed to opiate withdrawal is scored.*	**11. Gooseflesh skin**
0 Not present	0 Skin is smooth
1 Mild diffuse discomfort	3 Piloerection of skin can be felt or hairs standing up on arms
2 Patient reports severe diffuse aching of joints/muscles	5 Prominent piloerection
4 Patient is rubbing joints or muscles and is unable to sit still because of discomfort	
6. Runny nose or tearing: *not accounted for by cold symptoms or allergies*	
0 Not present	**Total Score:** _____
1 Nasal stuffiness or unusually moist eyes	[The total score is the sum of all 11 items.]
2 Nose running or tearing	Initials of person completing assessment:
4 Nose constantly running or tears streaming down cheeks	_____

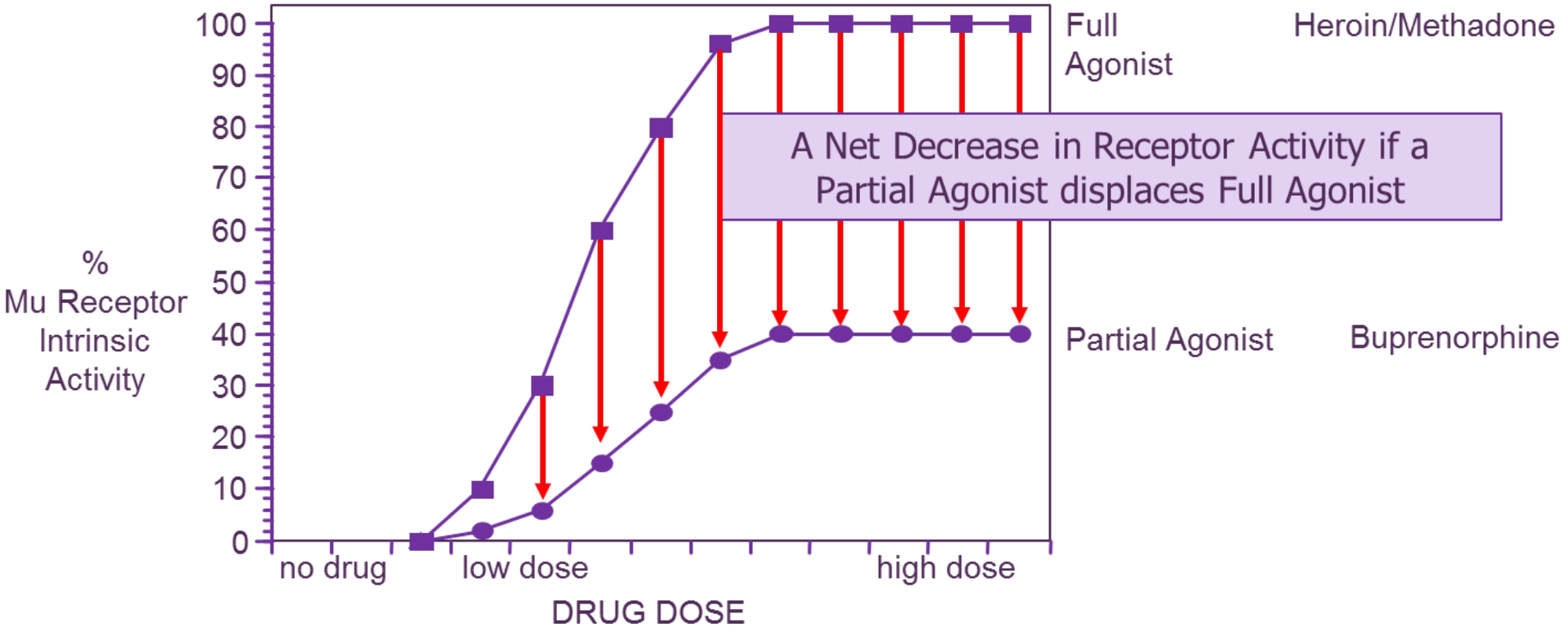
Score: 5-12=Mild; 13-24=Moderate; 25-36=Moderately severe; >36=Severe withdrawal.

Reference: Wesson, DR, Ling W, 2003. The clinical opiate withdrawal scale (COWS). J. Psychoactive Drugs 35, 253–259.

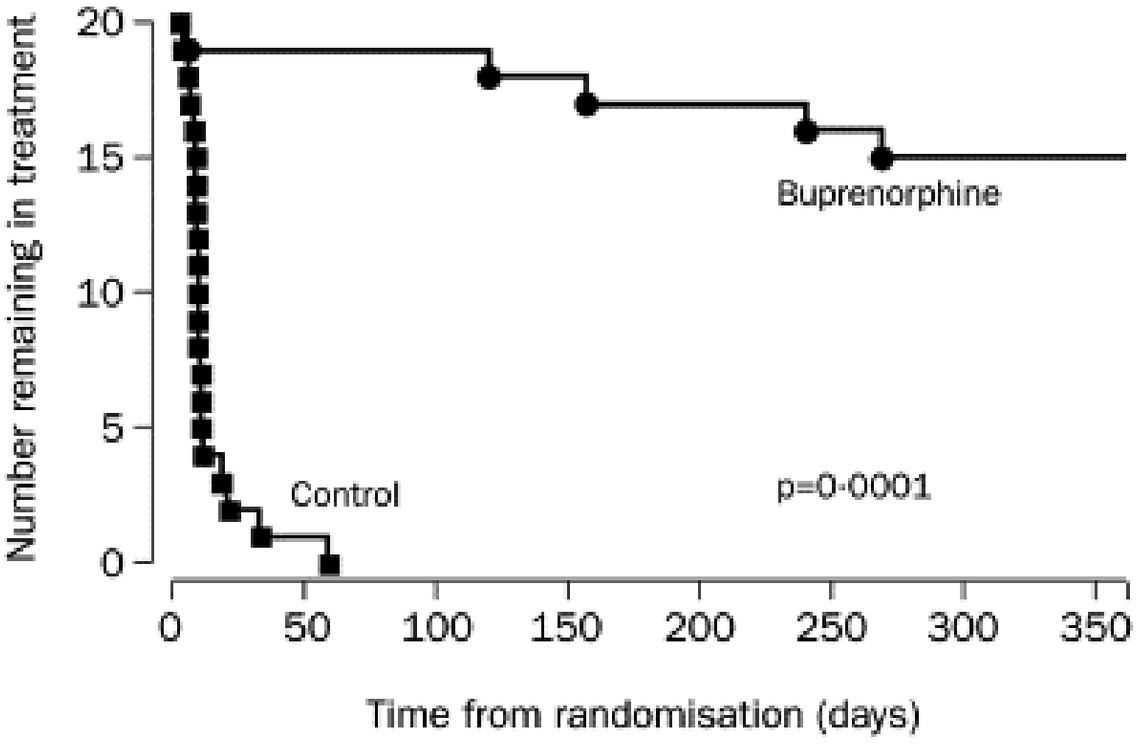
Wesson DR, Ling W, 2003.

PRECIPITATED WITHDRAWAL

- Buprenorphine can precipitate withdrawal if it displaces a full agonist from the mu receptors
- Buprenorphine only partially activates the receptors; therefore, a net decrease in activation occurs and withdrawal develops



1-YEAR RETENTION AND SOCIAL FUNCTION AFTER BUPRENORPHINE-ASSISTED RELAPSE PREVENTION TREATMENT FOR HEROIN DEPENDENCE IN SWEDEN: A RANDOMISED, PLACEBO-CONTROLLED TRIAL



	Placebo	Bupre-norphine	Cox regression
Dead	4/20 (20%)	0/20 (0%)	χ^2=5.9; p=0.015

- Subjects were heroin-dependent patients who agreed to the study, and did not fulfill the criteria for methadone treatment
- Double-blind, random assignment to:
  - 16 mg/day SL buprenorphine tablets, or
  - 6 day buprenorphine withdrawal followed by placebo tablets
- 20 patients per group

Kakko J et al. Lancet. 2003 Feb 22;361(9358):662-8

PRESCRIPTION OPIOID ADDICTION TREATMENT STUDY (POATS)

- 653 treatment-seeking outpatients dependent on prescription opioids.
  - all received buprenorphine-naloxone
- Treatment phases
  - Phase 1: Brief treatment included 2-week buprenorphine-naloxone stabilization, 2-week taper, and 8-week postmedication follow-up.
  - Phase 2: unsuccessful patients entered phase 2
    - extended (12-week) buprenorphine-naloxone treatment, 4-week taper, and 8-week postmedication follow-up.
  - In both phases, patients were randomized to standard medical management (SMM) or SMM plus opioid dependence counseling.

Weiss, et al. (2011). Adjunctive counseling during brief and extended buprenorphine-naloxone treatment for prescription opioid dependence. *Archives of General Psychiatry*. 68(12):1238-1246. http://www.ncbi.nlm.nih.gov/pubmed?term=22065255

POATS STUDY RESULTS

- Phase 1: only 6.6% (43 of 653) of patients had successful outcomes
  - no difference between SMM and SMM plus opioid dependence counseling.
- Phase 2: 49.2% (177 of 360) attained successful outcomes during extended buprenorphine-naloxone treatment (week 12)
  - no difference between counseling conditions.
- 8 weeks after completing the buprenorphine-naloxone taper (phase 2, week 24) success rates dropped to 8.6% (31 of 360)
  - again with no counseling difference.
- In secondary analyses, successful phase 2 outcomes were more common while taking buprenorphine-naloxone than 8 weeks after taper (49.2% [177 of 360] vs 8.6% [31 of 360], $P < .001$).
- Chronic pain did not affect opioid use outcomes
- A history of ever using heroin was associated with lower phase 2 success rates while taking buprenorphine-naloxone.

Weiss, et al. (2011). Adjunctive counseling during brief and extended buprenorphine-naloxone treatment for prescription opioid dependence. *Archives of General Psychiatry*. 68(12):1238-1246. http://www.ncbi.nlm.nih.gov/pubmed?term=22065255

BUPRENORPHINE AVAILABLE PRODUCTS, 2018

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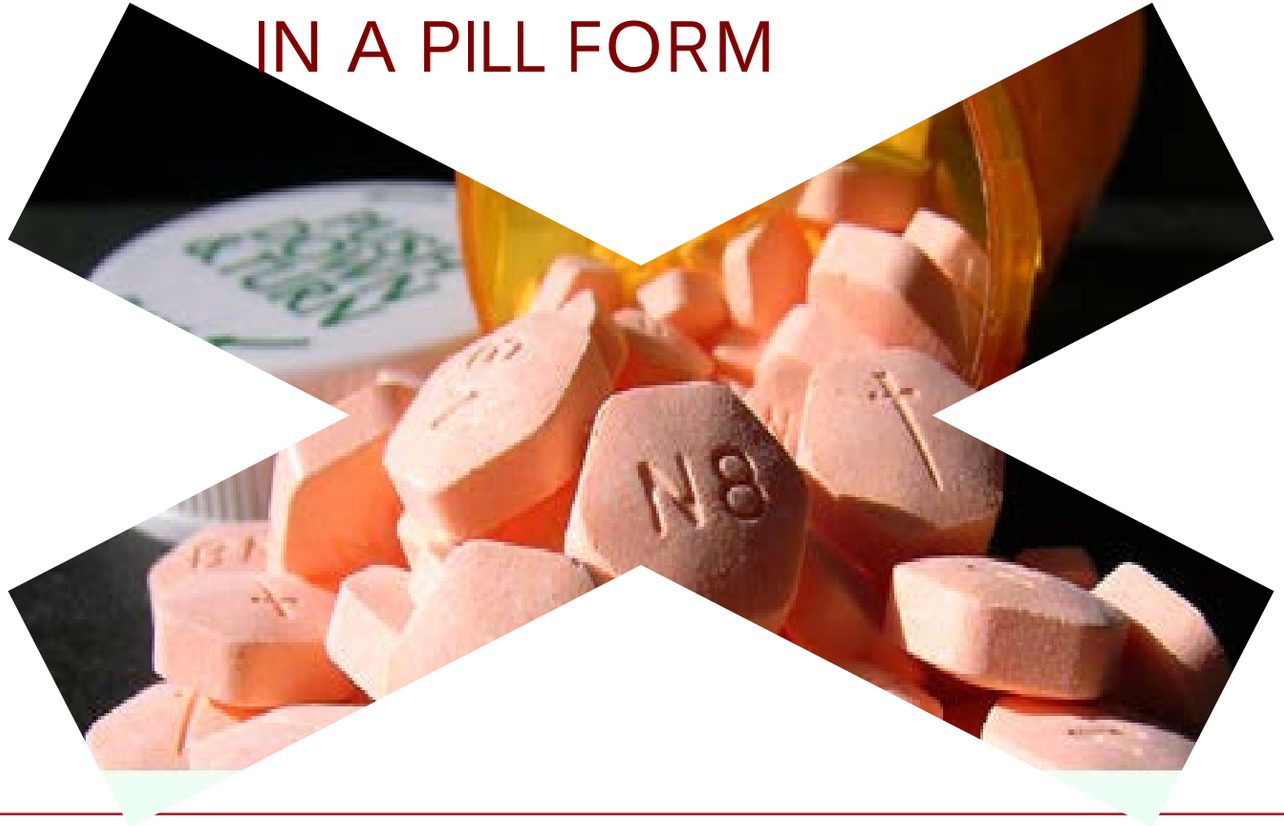
SUBOXONE® BRAND NAME IS NO LONGER AVAILABLE IN A PILL FORM



BUPRENORPHINE FORMULATIONS FOR ADDICTION TREATMENT

- Buprenorphine with Naloxone (combo product)
  - Generic sublingual tablets (Formerly Suboxone®)
  - Zubsolv® tablets, 0.7, 1.4, 5.7, 8.6, 11.4 mg tabs
  - Bunavail® buccal film 2.1, 4.2, 6.3 mg film
  - Sublingual film (Suboxone® and others in development) 2, 4, 8, 12 mg film
- Buprenorphine (mono product)
  - Sublingual tablets, formerly Subutex®
  - Implantable formulation (Probuphine®)
  - Extended release injection formulation (Sublocade®), available spring 2018
- ALL have Risk Evaluation and Mitigation Strategy (REMS) requirements

BUPRENORPHINE ONLY PRODUCTS

Product	Subutex	Belbuca	Butrans	Buprenex	Sublocade	Probuphine
FDA Indication	Opioid dependence	Pain requiring daily, around-the clock opioid treatment and for which alternative treatments are inadequate	Pain requiring daily, around-the clock opioid treatment and for which alternative treatments are inadequate	Pain requiring an opioid analgesic and for which alternate treatments are inadequate	Moderate to Severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days.	Maintenance treatment of opioid dependence in patients who have achieved and sustained prolonged clinical stability on low-to-moderate doses of transmucosal buprenorphine
Dosage Form	Sublingual Tablets	Buccal Films	Transdermal weekly patch	IV or IM Injection	Monthly SQ Injection	Subdermal 6 Month Implant
Strengths Available	2 and 8 mg	75, 150, 300, 450, 600, and 750 mcg	5, 7.5, 10, 15, 20 mcg/hr	0.3 mg/ml	100mg/0.5 ml and 300mg/1.5 ml	74.2 mg
Generic Available	Yes	No	No	Yes	No	No

BUPRENORPHINE ONLY PRODUCTS

Subutex SL tablets	Belbuca buccal films	Butrans transdermal weekly patch	Buprenex injection IV or IM	Sublocade monthly SQ injection	Probuphine SD 6 month implant
2mg	75mcg	5mcg/hr	0.3mg/ml	100mg/0.5ml	74.2mg
8mg	150mcg	7.5mcg/hr		300mg/1.5ml	
	300mcg	10mcg/hr			
	450mcg	15mcg/hr			
	600mcg	20mcg/hr			
	750mcg				
	900mcg				

BUPRENORPHINE/NALOXONE PRODUCTS

Product	Suboxone Tablets	Suboxone Films	Zubsolv	Bunavail	Cassipa
FDA Indication	Treatment of Opioid Dependence				
Dosage Form	Sublingual Tablets	Sublingual Films	Sublingual Tablets	Buccal Film	Sublingual Film
Strengths Available	2/0.5 mg 8/2 mg	2/0.5 mg 4/1 mg 8/2 mg 12/3 mg	0.7 / 0.18 mg 1.4 / 0.36 mg 2.9 /0.7 mg 5.7 /1.4 mg 8.6mg / 2.1mg 11.4mg / 2.9mg	2.1 mg / 0.3 mg 4.2 mg / 0.7 mg 6.3 mg / 1 mg	16/4 mg
Generic Available	Yes	No (was temporarily available now anticipated 2020)	No	No	Yes

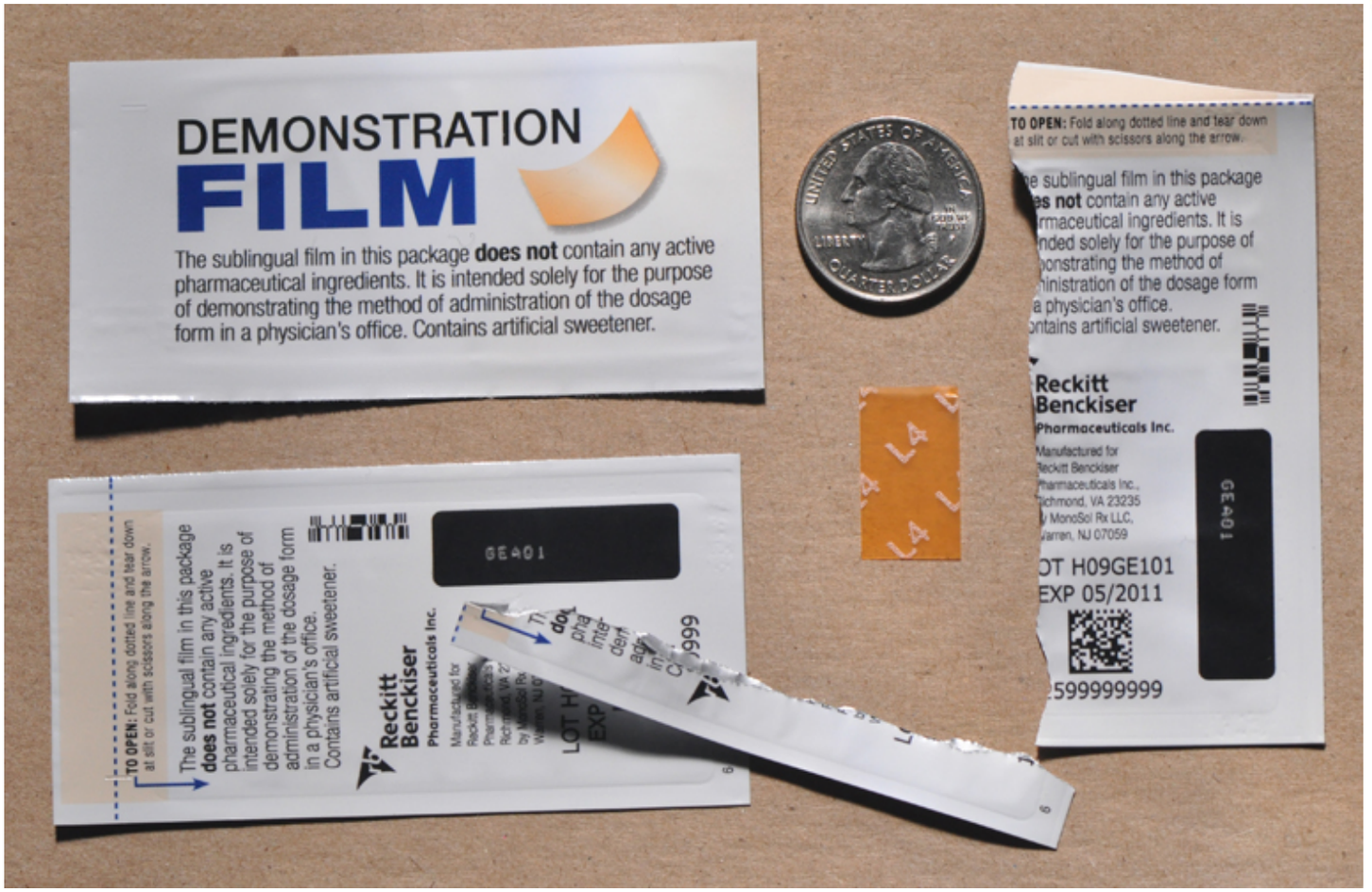
BUPRENORPHINE/NALOXONE PRODUCTS

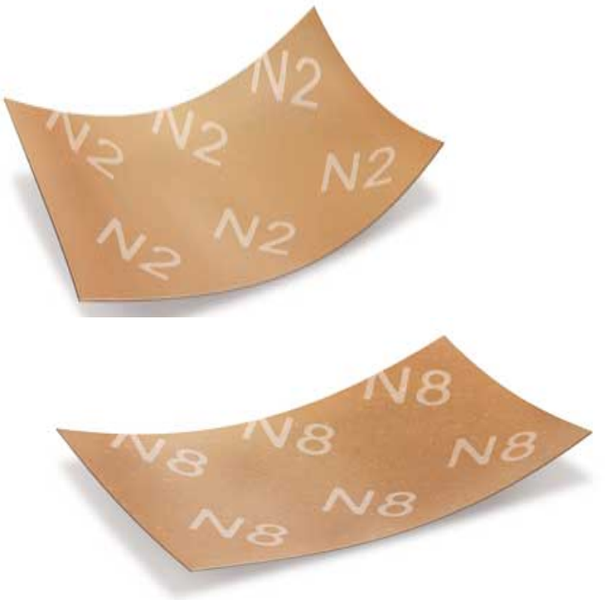
Suboxone SL Tablet	Suboxone SL Film	Zubsolv SL Tablet	Bunavail Buccal Film	Cassipa SL film
2 mg / 0.5 mg	2 mg / 0.5 mg	0.7mg / 0.18mg	2.1 mg / 0.3 mg	16mg /4mg
8 mg /2 mg	4 mg / 1 mg	1.4 mg / 0.36 mg	4.2 mg / 0.7 mg	
	8 mg / 2 mg	2.9mg /0.71mg	6.3 mg / 1 mg	
	12 mg / 3mg	5.7mg/ 1.4mg		
		8.6mg / 2.1mg		
		11.4mg / 2.9mg		

EQUIVALENCY OF BUPRENORPHINE-CONTAINING PRODUCTS

Product	Generic Subutex Tablets	Generic Suboxone Tablets	Suboxone Films	Zubsolv	Bunavail	Cassipa
Equivalent Dosages	2 MG	2 / 0.5 MG	2 / 0.5 MG	1.4 / 0.36 MG	N/A	N/A
	8 MG	8 / 2 MG	8 / 2 MG	5.7 / 1.4 MG	4.2 / 0.7 MG	8/2 MG (½ Film)
Cost Per Day (assuming 8mg subutex equivalence)	$1.62	$3.8	$8.15	$8.3	$7	?

BUPRENORPHINE-NALOXONE SUBLINGUAL FILM (SUBOXONE®)

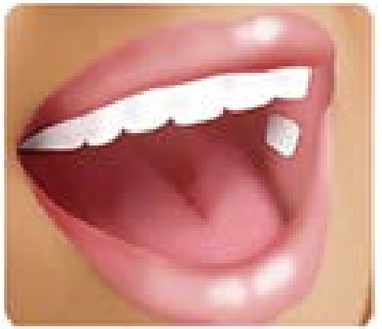




Dosages: 2 mg buprenorphine/0.5 mg naloxone; 4 mg/1 mg; 8 mg/2 mg; 12 mg/3 mg
No current generic film

BUPRENORPHINE-NALOXONE BUCCAL FILM (BUNAVAIL®)

ADHERES → DISSOLVES → DELIVERS



- Bi-layered film technology
- Active drug in the muco-adhesive layer
- Backing layer facilitates unidirectional flow of drug

- Adheres to oral mucosa in < 5 seconds
- Completely dissolves within 15-30 minutes
- Minimal taste issues

- Rapid drug absorption
- Designed to optimize delivery across the mucosa

Dosages:
2.1 mg bup/ 0.3 mg nx;
4.2 mg/0.7 mg;
6.3 mg/1 mg.

No current generic buccal film.

BUPRENORPHINE IMPLANTABLE RODS (PROBUPHINE®)

Figure 5

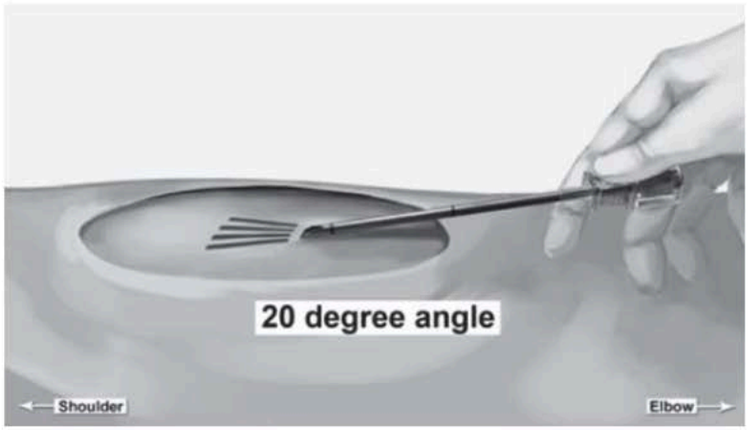


Figure 6

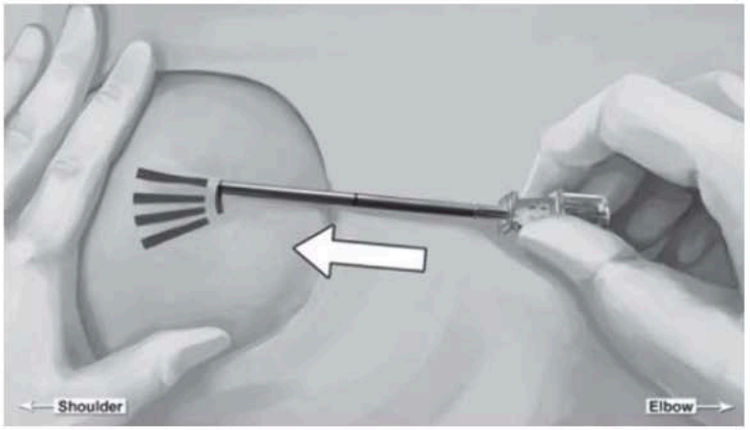
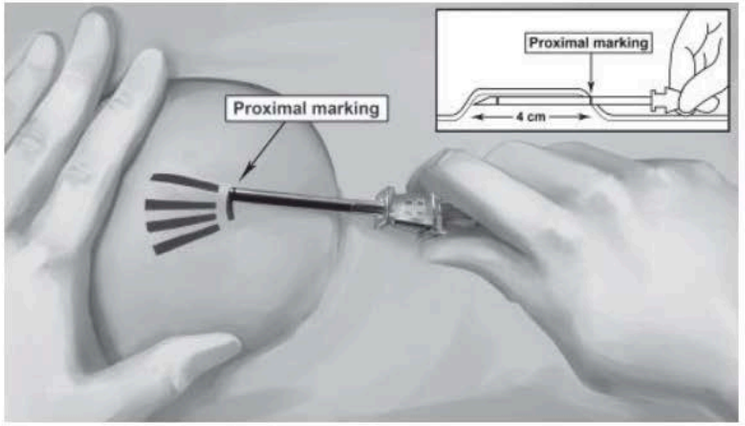


Figure 7



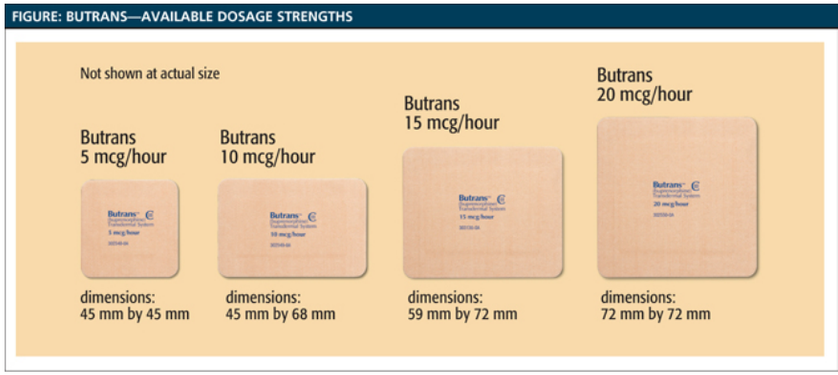
- Special training required to prescribe and/or implant
- Minor surgery for implant and removal
- Lasts 6 months
- For more stable patients on 8 mg or less buprenorphine daily

XR BUPRENORPHINE INJECTABLE (SUBLOCADE®)

- FDA-approved Nov 2017
- Available spring 2018
- Buprenorphine extended release
- Subcutaneous injection in abdominal region
- Monthly injection
- Dosages 100 mg/0.5 ml or 300 mg/1.5 ml
- For moderate or severe Opioid use disorder
- Pt must have been using transmucosal buprenorphine product for at least 7 days
- Recommended dose=two monthly initial doses of 300 mg followed by 100 mg monthly maintenance doses
- Must include counseling and support

BUPRENORPHINE FORMULATIONS FOR **PAIN** TREATMENT, NOT ADDICTION

- Injectable Buprenorphine (Buprenex®)
  - For pain only
  - Schedule III (was Schedule V until 2002)
  - **NOT FDA-approved for treatment of opioid addiction or detoxification**
- Transdermal patch (Butrans®)
  - For pain only
  - Expensive
  - **NOT FDA-approved for treatment of opioid addiction or detoxification**



ACQUISITION COSTS FOR VARIOUS PRODUCTS

Product	Cost
Buprenorphine 2mg and 8mg tabs	$0.80 and $1.15 each
Buprenorphine films Belbuca	$5 - $12.25 each
Buprenorphine/naloxone films Bunavail	$7 - $14 each
Suboxone tablets (generic)	$0.95 - $3.80
Suboxone films	$4.50 - $16 each
Cassipa 16 mg / 4 mg film	?
Butrans weekly patch	$60 - $160 each
Buprenex 0.3mg/ml injection (generic)	$5 per ml
Sublocade monthly SQ inj	$1,896 for 100mg dose
Probuphine 6 month implant	$1,485

RESTRICTED DISPENSE PROGRAM AT UNI

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RESTRICTED DISPENSING PROGRAM AT UNI

- Started in April 2013
- 60 patients currently in program
- No additional fee from pharmacy to participate
- Communication between pharmacy, patients and provider key to success

RESTRICTED DISPENSING PROGRAM AT UNI

- Details of restricted dispensing determined by provider
- Pharmacy needs to know who, if anyone, can pick up prescription for patient
- Medication is kept separate from other filled prescriptions
- Log books used to keep track of patients and notes are added to patients electronic medical record

RESTRICTED DISPENSING PROGRAM AT UNI - DOCUMENTATION

- Every patient has a log sheet which is updated with each pickup
- Log sheet contains
  - Medication
  - Dose
  - Dispense frequency
  - Pick-up day
  - Pick-up requirement ie, MAT group attendance, appointment w/ MD/IOP/after UA
  - Payment arrangement

RESTRICTED DISPENSING PROGRAM AT UNI

- Helpful hints for success
- Limit oversight to few employees but make sure information is well retrievable to everyone who works in the pharmacy
- Good communication with provider
- We have patient observe "counting" of films/tabs at time of pickup and sign receipt
- Pick up limited to one pharmacy location. Our patients cannot transfer or pick up remaining tabs/films at any other University pharmacy.

Thank you!