BuTrans Patch

Buprenorphine Transdermal System (BTDS) for Weekly Application

Classification[1,2]

{Semisynthetic, highly lipophilic opioid; derivative of morphine alkaloid thebaine; brain tissue levels far exceed serum levels}

- Opioid analgesic (mu agonist; kappa & delta antagonist). Narcotic and Controlled Drug (Canada). It is often considered a *partial* mu agonist; however some recent literature suggests full potent mu activity.[3] Its action may more resemble a full mu agonist at lower doses, and partial mu agonist at higher doses. Controversial!
  {Note, a related product, SUBOXONE consists of [buprenorphine 2mg + naloxone an opioid antagonist 0.5mg] as a SL tablet used to treat opioid dependence. Bioavailability of buprenorphine-variable: Transdermal ≅ 15%; SL= 30%-70%; Suboxone usual dosage range is 4-24mg/day buprenorphine. The amount of opioid equivalency is uncertain; however, the 20mcg/hr patch is considered to be ≤ 50 MED. Only ~ 3% of the naloxone is absorbed; it will precipitate withdrawal if injected; ∴ useful in OUD.

Strengths

- Patch (matrix): **5mcg/hr** (0.12mg/day), **10mcg/hr** (0.24mg/day), **20mcg/hr** (0.48mg/day); **15mcg/hr** also now available

Use/Place in Therapy

- Persistent pain of moderate intensity in adults (≥40kg) requiring continuous opioid analgesia for an extended period of time (not suitable for unstable or widely fluctuating pain). [Higher patch strengths e.g. TRANSTEC 35-70mcg/hr (q3d) available in Europe for pain.[4]]
- Can be used in opioid naïve patients (alternate to codeine, tramadol) and patients previously only on prn opioids
- Considered when non-opioids provide inadequate relief and strong opioids undesirable in chronic non-cancer pain

Contraindications (CI), official [1 CPS]

- Hypersensitivity, GI (ileus, surgical abdomen), mild/intermittent/acute pain, acute asthma/obstructive airway/respiratory depression, acute alcoholism/dependence, opioid dependence/acute opioid withdrawal, convulsive disorders, MAOIs within 14 days, myasthenia gravis, hepatic insufficiency, pregnancy/lactation; <40kg

Dose

{Patch provides sustained levels & analgesia over 7 days.}

{High affinity for mu receptor ⇨blockade may last >24hrs. Effect not totally related to plasma levels.}

- **Begin at:** ◆ 5mcg/hr patch applied once weekly; titrate up as necessary or
  ◆ if previously on opioid (**up to 80mg oral morphine equivalent/day**) may start on 5-10mcg/hr patch once weekly (medication for breakthrough pain should also be provided)
- **Dose adjustments**: generally recommended after 7 days; and not more frequently than after 3 days.
- **Maximum dose**: 20mcg/hr. (Patch applied for 7 days.) Doses ≥40mcg/hr may be associated with QT prolongation (but less than methadone)![5]
- **Breakthrough pain**: may be managed by acetaminophen or NSAID +/- codeine or other breakthrough meds prn
- **Adjustments**: Renal dysfx: NO dose adjustment required; (hepatic metabolism glucuronidation & biliary excretion).

Administration

- Apply to: non-irritated, dry, intact skin; upper outer arm, upper chest, upper back or side of chest (always above the umbilicus)
  - Do not apply creams or ointments etc. to skin < 6hours prior to patch application as may affect adhesion.
  - If site irritation, consider a corticosteroid spray (e.g. beclomethasone or fluticasone) to skin area prior to patch; (this lacks data & may affect absorption). {Alternately, steroid cream post-patch or well in advance (> 6-12hr) of patch application.}
- Rotate sites with each new patch; choose 4 or more sites and rotate; **allow 3 weeks** before reusing the same site
- Avoid exposure of patch to direct sunlight ✹ (↑ absorption). Showering, swimming & bathing should not affect patch.

Drug Interactions (DI)

Metabolized via CYP3A4 to nor-buprenorphine (an active metabolite).

- 3A4 inhibitors: ↑ dose related toxicity of buprenorphine e.g. amiodarone, itraconazole, clarithromycin, fluconazole, erythromycin, grapefruit juice, protease inhibitors ritonavir, nelfinavir, amprenavir, verapamil, diltiazem
- 3A4 inducers: likely to ↓ efficacy of buprenorphine: e.g. phenobarbital, carbamazepine, phenytoin, rifampin
- CNS depressants: additive effects (e.g. ↑sedation, ↓ alertness, confusion, dizziness)
  - E.g. alcohol, benzodiazepines, sedative/hypnotics, antipsychotics, antihistamines
- Other: Warfarin ↑ INR; anesthetics ↓ hepatic blood flow & ↑ [buprenorphine]; Benzodiazepines flunitrazepam: deaths reported in addict population

Adverse Events (AE)

{Most are similar to other opioids.}

- Common on initiation: nausea[45%], dizziness[27%], somnolence[24%], constipation[21%], pruritus, dry mouth
- Most common in clinical trials (rates from crossover trials; for difference from placebo rates, see CPS or specific trial literature):
  - anorexia, application site erythema/pruritis[25%], asthenia, constipation, dizziness[27%], dry mouth, headache, hyperhydrosis[16%], insomnia, nausea +/- vomiting, somnolence. [Potential QT prolongation with ≥40mcg/hr patch.]
- Serious, but less common with careful dose titration: respiratory depression however ceiling effect in resp depression, hypotension

Discontinuing / Withdrawal

- Consider tapering if higher doses to reduce withdrawal symptoms; withdrawal generally mild & resolves in ≤2 weeks
- After removal of patch, levels decline gradually; ~ 50% ↓ over ~12hours (10-24 hrs); administering a subsequent opioid after patch removal should generally be delayed until 24hours after removal

Other

Cost / 4 weeks:
5mcg/hr: $ 60
10mcg/hr: $ 105
20mcg/hr: $ 185
(includes markup & dispensing fee)
Currently not covered by most drug plans!

- Steady state levels in ~3 days. Heat sources (external): will ↑ absorption & risks (e.g. heat pad, hot bath, sauna, sunbathing, fever, etc.)
- **Advantages**: long action useful for chronic-stable type pain; once weekly application & kappa antagonist effect may result in less dysphoria, psychological craving & dependence {However, data from Norway suggests addiction concerns}[6]. May cause less withdrawal when stopped than other opioids; incidence of constipation may be lower.
  Compared to the fentanyl patch: lower abuse potential, mild withdrawal symptoms, may initiate in opioid naïve.
- **Disadvantages**: long & delayed action means it is not suitable for acute or fluctuating pain; adverse effects may be sustained for ≥ 24 hours after removal of patch. {If one holds that it is a partial mu agonist, this would limit the opioid effect resulting in both a ceiling dose & potential withdrawal in patients dependent on other long-term opioids.}. Studies are short term (e.g. ≤12 weeks; most ≤4weeks); results modest & benefits ≅ harms (NNT = 7-8 & NNH for ↑AE = 6-9).
- CEDAC (Sept-2011 CDR Update): recommends against listing for coverage; high cost but no more effective than PO opioids

Estimated Dose Equivalencies: BuTrans (BTDS) may be 25–110x more potent than oral morphine; individual variance; highly controversial!!![7]

	Daily Opioid Dose* [1,5,8,9] & Approximate Cost/4wks					
Acetaminophen + Codeine (30mg) ± Caffeine	≤6 (x30mg) tabs		7-8 (x30mg) tabs	$43		
Codeine	≤100mg		200 mg	$67	400 mg	$89
Tramadol	-		150 mg	$56	300 mg	$100
Oral Morphine	≤15 mg		30 mg	$30	60 mg	$42
Oral Oxycodone	≤10 mg		15 – 20 mg	$64	30 -40 mg	$92
Oral Hydromorphone	≤3.75 mg		6 – 7.5 mg	$51	12 – 15 mg	$72
Fentanyl Patch	-		-		12 mcg/hr	$42
	⬇		⬇		⬇	
Initial BuTrans patch dose if on previous opioid.	**5 mcg/hr**		**5 mcg/hr** + something for breakthru		**5-10 mcg/hr** + something for breakthru	
Estimate of Eventual BuTrans® Patch Strength	5 mcg/hr	$60	10 mcg/hr	$105	20 mcg/hr *	$185

Cost/week based on lowest cost sustained release (SR) formulations.

Note however that **opioid withdrawal** may occur for patients taking long-term and/or higher doses of opioids after switching to buprenorphine!**

*Monograph does not recommend starting > than 10 mcg/hr (as per "dosing" above). Table serves as a guide; actual dosing requires careful individualization & reassessment!

**** Can patients on high doses of morphine &/or strong opioids be switched to transdermal buprenorphine?** (See also extras under page 3 of this Q&A online.)

Currently this is not recommended in Canada and there is concern about opioid withdrawal. **However**, one study successfully switched cancer patients on oral morphine (120-240mg/d) and transdermal fentanyl (50-100mcg/hr) to BTDS using a potency ratios of 70:1 for morphine and 0.6:0.8 for transdermal fentanyl.[10] Note, due to transdermal route, there is less bioavailability variance than oral opioids.

Anecdotally, some physicians report success with direct switching of **<40-60mg/day morphine equivalent** opioid regimens. Approach 1: wean patient over several weeks to about half their opioid dose, then convert to estimated equivalent buprenorphine dose +/- fast acting opioid. Approach 2: Apply first dose of equivalent dose buprenorphine patch at same time as taking last dose of long-acting opioid +/- fast acting opioid.

Table 1: Randomized controlled trials (RCT): buprenorphine transdermal system (BTDS) - BuTrans (7 day) patch, chronic non-cancer pain

	Patients	Intervention	Results (primary; other)	Comments (General: industry sponsored trials)
1.[11]	**Low back pain,** mod-sev (VAS ≥2/5) for ≥6wks & not well controlled. (most had long hx) ◆n=53 (28♂; 25♀); age ~54 ◆baseline pain: 62.1 +/- 15.5	**BTDS** 5, 10, 20mcg/hr **vs PI** + i-ii ACC30 q4-6h prn lower dose for BTDS ◆DB, crossover @**4wk** ◆Not ITT (only evaluated if ≥ 2 wks tx completed)	◆↓ VAS: 37.6 +/- 20.7 vs 43.6 +/- 21.2 p=0.049 ◆use of breakthru tabs: 1.8 vs 2.4/day (NS) ◆also improved: pain +: sleep, disability, etc. ◆AE "severe" as per patient: 53% vs 42% NNH=9 ◆AE: >20%: (nausea, somnolence, pruritis, asthenia, constipation, insomnia, dizziness)	◆Exclusions: multiple (e.g. if expected to exceed max BTDS dose) ◆79 patients enrolled; 53 patients evaluated per-protocol ◆most patients (59%) titrated to highest dose (titrations weekly) ◆82% of patients chose to continue for 6 month open label follow-up where pain and QOL improvements were sustained ◆similar improvements in opioid & opioid naïve patients
2.[12]	**Low back pain,** mod-sev, on prior opioid (78 randomized) ◆PP: n=53 (20♂; 30♀); age ~51	**BTDS** 10, 20, 40mcg/hr **vs PI** + i-ii Acetaminophen q4-6h prn ◆DB, crossover @**4wk** ◆Not ITT	◆Mean dose = 29.8mcg/hr vs 32.9mcg/hr ◆PP: Pain on 0-4 point scale: 1.9 vs 2.2 p=0.044; no difference in pain disability index	◆BTDS had modest benefit vs PL considering prior opioid hx ◆Some +ve 2° outcomes: e.g. get out of bed, sit in chair. ◆ 6mo follow-up open label, 27/40 completed +ve. limitations: not ITT;↑ AEs
3.[13]	**Osteoarthritis** (hip or knee); mod-sev ◆n=135; age ~64 ◆baseline pain: ≥4 (BS-11) on acetaminophen 4g/day	**BTDS** 5, 10, 20mcg/hr **vs Tramadol CR** 150 - 400mg/day (+ acetaminophen prn) **x 12 wk** ◆Open label; non-inferiority	◆BS-11: no difference; - 2.26 vs -2.09 (ITT) ◆also rescue med; sleep; QOL ◆AE: 226 vs 152; AE⇨DC: 14.5% vs 29.2% ◆AE-BTDS: nausea 30%; constip. 19%; dizzy 16% ◆AE-Tramadol: nausea25%, fatigue18%, pain 12%	◆1wk screening, 12 wk treatment; 2 week follow-up phases; 172 screened, 135 randomized. ◆baseline pain: BS-11: 6.16⇨3.92 vs 6.21⇨4.10 (ITT) ◆patient and assessor ratings of pain favoured BTDS
3.[14]	**Osteoarthritis** (hip or knee); mod-sev ◆n=238 at run in; 102 42% analysed (~65%♀); age ~64 ◆ baseline pain: ≥4 (BS-11); no recent strong opioid	**BTDS** 5, 10, 20mcg/hr **vs buprenorphine SL** 0.2-0.4mcg q6-8h (+ acetaminophen ≤1g prn) ◆DB, **x ≤ 4wks**	◆BS-11: scores considered equivalent (per protocol) for morning, midday & evening ◆AE: patch associated with less nausea, vomiting & dizziness ◆Discontinuation (ITT): 53% vs 55% p=0.7; 42% discontinued due to AE	◆21 day run-in ◆6 serious adverse events: 1 fatal MI, not deemed related to BTDS; 1 hospitalization for biliary colic/spasm & 1 hospitalization for dizziness & asthenia. ◆patch site redness 55% & irritation 25%; some complaints of patch buckling or curling.
4.[15]	**Osteoarthritis** (hip or knee); n=315 at run-in;155 49% analyzed ◆age ~ 60, (67% ♀) ◆previously on opioid (≤90mg morphine equivalent; not more than 12doses of short-acting opioid/day) or lack of relief with NSAID	**BTDS** 5, 10, 20mcg/hr **vs PI** (no rescue medication allowed) DB, parallel group; **x 5 wks** (1 wk run-in, 3wk titration, 1wk maintenance) [blinding was broke for 1 patient]	◆patient satisfaction scale (0 – 4) at final visit: 44% vs 32% (ITT) satisfied score >2; OR=1.66 NNT=8; ◆AE: 70% vs 53%; NNH=6. (nausea, headache, dizziness, somnolence, pruitis at site, constipation.)	◆7 day run-in on ibuprofen & inadequate relief on ibuprofen ◆artificial type of trial ◆a number of 2° endpoints did not have significant differences but some "trends" supportive; ◆subgroup: benefit only seen in knee subgroup, not hip
5.[16]	**Non-cancer pain ≥2** months; on previous combination oral opioids ◆n=588 at run-in; n=267 45% actually randomized; (~62%♀); age ~57	**BTDS** 5, 10, 20mcg/hr **vs PI** (+ acetaminophen 500mg prn) ◆DB, parallel-group **x ≤ 2 wks** (discontinue early if require ≥1g acetaminophen/day, or unable to continue with patch)	◆proportion of subjects with ineffective tx: 51.2% vs 65%; NNT=7 ;(OR = 1.7995% CI: 1.09-2.95) ◆AE: pruritis at patch site 9.3% vs 5.1%; headache 3.9% vs 2.2% ; somnolence 2.3% vs 0.7%. (Open-label run-in withdrawal & early completion of study serve to underestimate true AE risks.)	◆Purdue sponsored; odd/unique design; very short! ◆Open label run-in with BTDS for 7-21 days; only those tolerating BTDS entered & randomization was at dose achieved during run-in (may underestimate harm & overestimate efficacy)
6.[17]	**Osteoarthritis** (hip or knee); mod-sev ◆n=199; age ~63	**BTDS** 5, **10**, 20mcg/hr **vs PI x 6 mo** (NSAID continued; + acetaminophen prn)	◆WOMAC OA Index of Pain (1°): NS ◆some 2°s improved: daytime movement pain	◆BTDS: ?less effective in very severe OA; ?patient preferred ◆no difference in BTDS & PI in mean dose or titrations required

Select Studies with different dose (e.g. 35-70mcg/hr) or dosage form (e.g. 3-4 day patch) than available in Canada; but of interest

1. [18]	**Chronic cancer pain** ◆open label; + tramadol ≤ 200mg/day prn	**BTDS 35** mcg/hr **vs Buprenorphine SL & PI**	◆pain ◆mental health & vitality; QOL	- dose higher than available in Canada
2. [19]	**Chronic cancer & non-cancer pain** ◆n=137 (90 BTDS; 47 PI) (~50% ♀)	**BTDS 35 - 70** mcg/hr **vs PI** (+ buprenorphine SL 0.2mg prn) ◆DB; **x 9 days**	◆breakthru pain as reflected by need for prn: ↓ use of buprenorphine 0.6 mg vs 0.4mg p=0.03. ◆patient's assessment of pain: NS. ◆nausea, dizzy & vomiting	◆6day open-label run-in with buprenorphine SL 0.8–1.6mg/day prn ◆72hr patch
3. [20]	**Chronic cancer & non-cancer pain** not controlled on weak opioids ◆n=157 (55% ♀); age 59	**BTDS 35 – 70** mcg/hr **vs PI** (+ buprenorphine SL 0.2mg prn) ◆DB; **x 15 days**	◆43.5% patients reported good pain relief vs 32.4% (NNT=9); response rate higher at 35-52.5mcg/hr, but NS at 70mcg/hr. ◆78% overall reported ≥1 AE (CNS & GI)	◆improved sleep reported ◆72hr patch used ◆↓ need for prn: 56.7% vs 8%;
4. [21]	**Chronic cancer & non-cancer pain** ◆n=445	**BTDS 35 - 70** mcg/hr **vs PI** ◆?	◆?greater pain relief vs PI	◆72hr patch used. ◆239 patients chose to continue BTDS in open follow-up study

ACC30=acetaminophen/caffeine/codeine 30mg AE=adverse events BS-11=box score 11 point rating system CR=controlled release DB=double-blind ITT=intention to treat NNH=number needed to treat to harm one patient NNT=number needed to treat to benefit one patient NS=not statistically significant OR=odds ratio. OUD=opioid use disorder PI=placebo QOL=quality of life SL=sublingual VAS=visual analogue scale

Additional References & Links

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Prepared by **Loren Regier**, **Sep 2010** (Update Dec/2011)for **RxFiles Academic Detailing** www.RxFiles.ca. Thanks to the many reviewers who provided input.

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[22] **Comments (anecdotal) from clinicians on switching from other opioids to BuTrans**

- Officially not recommended in Canada, but some experience has been positive
- Limited experience; if done, most success with tapering down the other opioids prior to switch to Butrans 5 or 10 and then titrated up as necessary. Direct opioid rotations mostly only for doses <40-60 mg/day of morphine.
- Encourage non-drug therapy complementary approaches in addition to drug therapy; essential for long term success of CNCP
- Relative potency for switching is not well established:
  - BuTrans 5 = .12 mg/day ≈ 10 mg/day morphine or 7.5 mg/day oxycodone
  - BuTrans 10 = .24 mg/day ≈ 20mg/day morphine or 15 mg/day oxycodone
  - BuTrans 20 = .48 mg/day ≈ 40 mg/day morphine or 30 mg/day oxycodone
- Example- pt on 40 mg morphine (Meslon 20mg bid) with poor pain relief (VAS 8/10)
  - Option #1 (preferred?) Wean patient down to 20mg/day (10 mg am 15mg pm X 1-2 weeks the 15mg BID X 1- 2 weeks the 10 mg am 15mg pm X 1-2 weeks then Sat am take last does of 10mg M-Eslon and apply BuTrans 10mg patch. Use MS-IR 5 mg bid prn for any withdrawal or severe pain
  - Option 2 = Patient on 20 mg M-Eslon bid; Sat am apply BuTrans 20 patch and take last dose of 20mg M-Eslon. Then use MS-IR 5-7.5 mg bid-tid severe pain or withdrawal.

  [MS-IR = immediate release morphine sulphate]