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# BUPRENORPHINE/NALOXONE (Bunavail, Suboxone, Zubsolv) Fact Sheet [G]

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## Bottom Line:

Buprenorphine/naloxone is the definitive partial agonist treatment for opioid use disorder (OUD). The combination product is preferred over buprenorphine alone for maintenance because it is the most widely available formulation and the addition of naloxone might lower its potential for misuse. The sublingual film formulation is priced a little higher than the sublingual tablets yet provides very little (if any) clinically meaningful benefit; generic tablets should be favored as a cost-saving measure.

## FDA Indications:

**OUD** (induction and maintenance).

## Dosage Forms:

- **SL tablets (G):** 2/0.5 mg, 8/2 mg (scored).
- **SL film strips (Suboxone, [G]):** 2/0.5 mg, 4/1 mg, 8/2 mg, 12/3 mg.
- **SL tablets (Zubsolv):** 0.7/0.18 mg, 1.4/0.36 mg, 2.9/0.71 mg, 5.7/1.4 mg, 8.6/2.1 mg, 11.4/2.9 mg.
- **Buccal film (Bunavail):** 2.1/0.3 mg, 4.2/0.7 mg, 6.3/1 mg.

## Dosage Guidance:

- Induction procedure:
  - Begin when opioid withdrawal reaches moderate severity; otherwise you may trigger more severe withdrawal symptoms.
  - Start 4–8 mg SL day 1; increase up to 16 mg on day 2; then up to 24 mg on day 3. Some patients may need up to 12 mg in first 24 hours.
- Maintenance treatment: Give combination product (Suboxone or [G]) daily in the equivalent buprenorphine dose on last day of induction; adjust dose in increments between 2 mg and 8 mg to a level that suppresses opioid cravings (usually 8–24 mg/day); best evidence is for 16–24 mg/day; max 32 mg/day.
- Some patients prefer taking smaller doses multiple times per day; can be a useful strategy for chronic pain patients.
- Zubsolv 5.7/1.4 mg SL tablet provides equivalent buprenorphine to Suboxone 8/2 mg SL tablet.
- Bunavail 4.2/0.7 mg buccal film provides equivalent buprenorphine to Suboxone 8/2 mg SL tablet.

**Monitoring:** No routine monitoring recommended unless clinical picture warrants.

**Cost:** SL tablet, film, Bunavail: \$–\$\$ depending on dose; Zubsolv: \$\$\$

## Side Effects:

- Most common: Constipation, headache, vomiting, sweating.
- Serious but rare: Hepatitis reported rarely, ranging from transient, asymptomatic transaminase elevations to hepatic failure; in many cases, patients had preexisting hepatic dysfunction. Rare cases of dental problems including tooth decay, cavities, and infections; recommend swishing with water after dose completely dissolved and good dental care.

## Mechanism, Pharmacokinetics, and Drug Interactions:

- Buprenorphine: Partial opioid agonist (delta and mu receptors) and antagonist (kappa receptors); naloxone: Opioid antagonist (mu receptor).
- Metabolized primarily through CYP3A4;  $t_{1/2}$ : 24–48 hours (naloxone: 2–12 hours).
- Avoid concomitant use with opiate analgesics (diminished pain control). Additive effects with CNS depressants. CYP3A4 inhibitors and inducers may affect levels of buprenorphine.

## Clinical Pearls:

- Schedule III controlled substance. Prescribing buprenorphine for OUD no longer requires having a special “X-license.”
- Naloxone is an opioid antagonist that is active only when injected; it is added to buprenorphine in order to reduce misuse via intravenous injection of a dissolved tablet.
- The SL film formulation’s manufacturer claims it dissolves faster and tastes better than SL tablets. Actually, it is more likely a way for the manufacturer to switch users to a “new” product (with patent protection until 2025) rather than lose patients to generics. There is no evidence to suggest that there is any clinical benefit.

- SL film should be placed at base of tongue to the side of midline; this allows patient to use two tablets or films at the same time if dose dictates.
- Zubsolv and Bunavail formulations have better bioavailability, hence the dose equivalencies noted above.
- Prescribers should be aware of the risk for diversion and sale of buprenorphine films and tablets. Buprenorphine is bought and sold on the streets typically to combat cravings and withdrawal symptoms.

**Fun Fact:**

The manufacturer of Suboxone, Reckitt Benckiser, generates most of its revenue from selling home and personal care products like Lysol cleaners and Durex condoms.