

NeuroBehavioral RECOVER™

June 1, 2004

Subutex® and Suboxone® Approved to Treat Opioid Dependence

In October of last year, the Food and Drug Administration (FDA) announced the approval of Subutex (buprenorphine hydrochloride) and Suboxone tablets (buprenorphine hydrochloride and naloxone hydrochloride) for the treatment of opiate

dependence. Subutex and Suboxone treat opiate addiction by preventing symptoms of withdrawal from heroin and other opiates.

supplied in 2 mg and 8 mg tablets which are placed under the tongue and must be allowed to dissolve.



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These products represent two new formulations of buprenorphine. The first of these formulations, Subutex, contains only buprenorphine and is intended for use at the beginning of treatment for drug abuse. The other, Suboxone, contains both buprenorphine and the opiate antagonist naloxone, and is intended to be the formulation used in maintenance treatment of opiate addiction. Naloxone has been added to Suboxone to guard against intravenous abuse of buprenorphine by individuals physically dependent on opiates. Both drugs are

The DEA has placed buprenorphine in Schedule III under the Controlled Substances Act. Buprenorphine is considered to have less risk for psychological and or physical dependence than the drugs in Schedule II such as morphine, oxycodone, fentanyl, or methadone.

Of Note:

- Buprenorphine is the only legal treatment for opioid addiction in the office based setting.
- The addition of naloxone deters diversion.
- Respiratory depression in overdose is limited by agonistic "ceiling effect".
- High tolerability and safety
- Treatment with buprenorphine may be particularly suited for prescription drug addicts.

Congress Brings Opioid Dependency Treatment to the Office

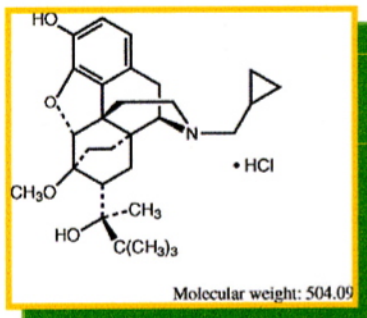
Subutex and Suboxone are the first narcotic drugs available for the treatment of opiate dependence that can be prescribed in an office setting under the Drug Addiction Treatment Act (DATA) of 2000.

Until recently, opiate dependence treatments in Schedule II, like methadone, could be dispensed in a very limited number of clinics that specialize in addiction treatment. As a consequence, there have not been enough addiction treatment centers to accommodate all patients desiring therapy.

Under this new law, medications for the treatment of opiate dependence that are subject to less restrictive controls than those of Schedule II can be prescribed in a doctor's office by specially trained physicians.

Buprenorphine's Agonistic "Ceiling Effect"

Buprenorphine is an opioid partial agonist. Although it can produce typical opioid agonist effects and side effects, such as euphoria and respira-



tory depression, its maximal effects are less than those of full agonists like heroin and methadone. At low doses, buprenorphine produces sufficient agonist effect to enable opioid-addicted individuals to discontinue the misuse of opioids without experiencing withdrawal symptoms.

The agonist effects of buprenorphine increase linearly with increasing doses of the drug until at moderate doses they reach a plateau and no longer continue to increase with fur-

ther increases in dose—the so-called "ceiling effect."

Thus, buprenorphine carries a lower risk of abuse, dependence, and side effects compared to full opioid agonists.

In fact, in high doses and under certain circumstances, buprenorphine can actually block the effects of full opioid agonists and can precipitate withdrawal symptoms in an acutely opioid-intoxicated individual.

The Role of Agonists in Addiction Treatment

Agonist therapy has been shown to be effective in opioid-dependence treatment. Patients receiving drug therapy have been shown to remain in chronic drug treatment programs at a rate 2.5 times greater than that of patients in self-help residential programs, and 5 times that of patients in drug-free outpatient treatment.

Agonists address the biological basis of opioid dependence and offer treatment options for physicians.

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Safety and Tolerability of Buprenorphine



range for sublingual tablets. Higher doses are unlikely to produce greater effects.

Side Effects

Side effects of buprenorphine are similar to those of other opioids and include nausea, vomiting, and constipation.

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