

Facts about Suboxone

1. What are Suboxone and Subutex?

Subutex and Suboxone are medications approved for the treatment of opiate dependence. Both medicines contain the active ingredient, buprenorphine hydrochloride, which works to reduce the symptoms of opiate dependence.

2. Why did the FDA approve two medications?

Subutex contains only buprenorphine hydrochloride. This formulation was developed as the initial product. The second medication, Suboxone contains an additional ingredient called naloxone to guard against misuse.

Subutex is given during the first few days of treatment, while Suboxone is used during the maintenance phase of treatment.

3. Will most prescriptions be for the Suboxone formulation?

Yes, Suboxone is the formulation used in the majority of patients.

4. How are Subutex and Suboxone different from the current treatment options for opiate dependence such as methadone?

Currently opiate dependence treatments like methadone can be dispensed only in a limited number of clinics that specialize in addiction treatment. There are not enough addiction treatment centers to help all patients seeking treatment. Subutex and Suboxone are the first narcotic drugs available under the Drug Abuse Treatment Act (DATA) of 2000 for the treatment of opiate dependence that can be prescribed in a doctor's office. This change will provide more patients the opportunity to access treatment.

5. What are some possible side effects of Subutex and Suboxone?

(This is NOT a complete list of side effects reported with Suboxone and Subutex. Refer to the package insert for a more complete list of side effects.)

The most common reported side effect of Subutex and Suboxone include:

- cold or flu-like symptoms
- headaches
- sweating
- sleeping difficulties
- nausea
- mood swings.

Like other opioids Subutex and Suboxone have been associated with respiratory depression (difficulty breathing) especially when combined with other depressants.

6. Are patients able to take home supplies of these medicines?

Yes. Subutex and Suboxone are less tightly controlled than methadone because they have a lower potential for abuse and are less dangerous in an overdose. As patients progress on therapy, their doctor may write a prescription for a take-home supply of the medication.

Buprenorphine Program

7. How will FDA know if these drugs are being misused, and what can be done if they are?

FDA has worked with the manufacturer, Reckitt-Benckiser, and other agencies to develop an in-depth risk-management plan. FDA will receive quarterly reports from the comprehensive surveillance program. This should permit early detection of any problems. Regulations can be enacted for tighter control of buprenorphine treatment if it is clear that it is being widely diverted and misused.

8. What are the key components of the risk-management plan?

The main components of the risk-management plan are preventive measures and surveillance.

Preventive Measures include:

- education
- tailored distribution
- Schedule III control under the Controlled Substances Act (CSA)
- child resistant packaging
- supervised dose induction

The risk management plan uses many different surveillance approaches.

Some active methods include plans to:

- Conduct interviews with drug abusers entering treatment programs.
- Monitor local drug markets and drug using network areas where these medicines are most likely to be used and possibly abused.
- Examine web sites.

Additionally data collection sources can indicate whether Subutex and/or Suboxone are implicated in abuse or fatalities. These include:

DAWN—The Drug Abuse Warning Network. This is run by the Substance Abuse and Mental Health Services Administration (SAMHSA) which publishes a collection of data on emergency department episodes related to the use of illegal drugs or non-medical use of a legal drug.

CEWG—Community Epidemiology Working Group. This working group has agreed to monitor buprenorphine use.

NIDA—National Institute of Drug Abuse. NIDA will send a letter to their doctors telling them to be aware of the potential for abuse and to report it if necessary.

9. Who can prescribe Subutex and Suboxone?

Only qualified doctors with the necessary DEA (Drug Enforcement Agency) identification number are able to start in-office treatment and provide prescriptions for ongoing medication. CSAT (Center for Substance Abuse Treatment) will maintain a database to help patients locate qualified doctors.

10. How will Subutex and Suboxone be supplied?

Both medications come in 2 mg and 8 mg strengths as sublingual (placed under the tongue to dissolve) tablets.

11. Where can patients get Subutex and Suboxone?

These medications will be available in most commercial pharmacies. Qualified doctors with the necessary DEA identification numbers will be encouraged to help patients locate pharmacies that can fill prescriptions for Subutex and Suboxone.

12. Where can I go for more information?

Go to:

http://www.fda.gov/cder/drug/infopage/subutex_suboxone/default.htm

Contact the CSAT Buprenorphine Information Center at 866-BUP-CSAT, or via email at info@buprenorphine.samhsa.gov or

<http://buprenorphine.samhsa.gov/>