European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

SUBOXONE

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Suboxone?
Suboxone are white, hexagonal, sublingual tablets (they dissolve under the tongue). Suboxone contains two active substances, buprenorphine and naloxone. The tablets contain either 2 mg buprenorphine and 0.5 mg naloxone, or 8 mg buprenorphine and 2 mg naloxone.

What is Suboxone used for?
Suboxone is used by drug addicts who have agreed to be treated for their addiction, as a substitution treatment for the opioid drugs they normally use. Opioids, also known as narcotic drugs, are drugs such as heroin or morphine. Suboxone is used in adults and children over the age of 15, who are also receiving medical, social and psychological support.
The medicine can only be obtained with a special prescription.

How is Suboxone used?
Suboxone must be used under the supervision of a doctor who has experience in the management of opioid addiction. The patient's liver function must be checked before the medicine is prescribed. The way Suboxone is used depends on the patient's status: type of addiction, state of withdrawal, and whether the patient is already using another substitution treatment such as methadone before starting Suboxone.
The recommended starting dose is one or two tablets of Suboxone 2 mg/0.5 mg. This dose is adjusted according to the patient's response, until the patient is stabilised. The dose should not be higher than 24 mg buprenorphine per day. Once the patient is stabilised, the dosage schedule can be adjusted or decreased. For the full dosage instructions, see the Summary of Product Characteristics, also part of the EPAR.
The tablets must be placed under the tongue and allowed to dissolve (this may take 5 to 10 minutes).

How does Suboxone work?
Suboxone contains two active substances, buprenorphine, which is an opioid agonist (it acts like an opioid drug), and naloxone, which is an opioid antagonists (it counteracts the effects of opioid drugs). Buprenorphine on its own, as sublingual tablets, has been used since the mid-1990's as a substitution treatment for opioid addiction. But the tablets have been misused: addicts have been known to dissolve them to inject the resulting solution. Suboxone contains buprenorphine with naloxone, because naloxone helps prevent the misuse of the medicine. Naloxone is not absorbed orally, but if injected to an opioid addict, it causes acute withdrawal symptoms.

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How has Suboxone been studied?
The effects of Suboxone were first tested in experimental models before being studied in humans.
The main study of the effectiveness of Suboxone compared Suboxone to buprenorphine on its own or to placebo (dummy treatment) in 326 opioid-dependent (heroin) patients. The study lasted 4 weeks, and measured the percentage of patients who had no trace of opioids in their urine at the end of the study. Patients also used a specially designed questionnaire to record their cravings, and the change in the questionnaire score before and at the end of the study was also measured.

What benefit has Suboxone shown during the studies?
Suboxone was more effective than placebo: 17.8% of the patients who received the medicine had a urine sample that tested negative at the end of the study, whereas the percentage was 5.8% in patients receiving placebo. The craving score, which was between 62.4 and 65.6 before treatment, was down to 29.8 with Suboxone (and 55.1 with placebo). The study also showed that there is no difference in the effectiveness of Suboxone when compared to buprenorphine on its own.

What is the risk associated with Suboxone?
The most common side-effects (seen in more than 1 patient in 10) are insomnia (difficulty sleeping), constipation, nausea (feeling sick), sweating, headache, and withdrawal syndrome. For the full list of all side effects reported with Suboxone, see the Package Leaflet.
Suboxone should not be used in people who may be hypersensitive (allergic) to buprenorphine or naloxone, or to any of the other ingredients. It should not be used in patients with severe lung insufficiency, severe liver insufficiency, or acute alcohol intoxication or *delirium tremens* (a condition brought on by alcohol withdrawal).

Why has Suboxone been approved?
The Committee for Medicinal products for Human Use (CHMP) concluded that the combination of an opioid analogue with an opioid antagonist is an established strategy for reducing the potential for intravenous misuse. They decided that Suboxone's benefits as a substitution treatment for opioid drug dependency are greater than its risks and they recommended that Suboxone be given marketing authorisation.

Which measures are being taken to ensure the safe use of Suboxone?
The company who markets Suboxone will put together information plans for doctors and pharmacists, to ensure that they are aware of the risk of misuse, and that they report on specific safety issues with the medicine such as liver disorders and effect on newborns.

Other information about Suboxone:
The European Commission granted a marketing authorisation valid throughout the European Union for Suboxone to SP Europe on 26 September 2006.

The full EPAR for Suboxone can be found here.

This summary was last updated in 08-2006.