EMA/764285/2015
EMEA/H/C/000697

EPAR summary for the public

Suboxone

buprenorphine / naloxone

This document is a summary of the European public assessment report (EPAR) for Suboxone. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Suboxone.

What is Suboxone?

Suboxone is a medicine that contains two active substances, buprenorphine and naloxone. It is available as sublingual tablets containing 2 mg buprenorphine and 0.5 mg naloxone, 8 mg buprenorphine and 2 mg naloxone, or 16 mg buprenorphine and 4 mg naloxone. 'Sublingual' means that the tablet is placed under the tongue where it dissolves.

What is Suboxone used for?

Suboxone is used to treat dependence on opioid (narcotic) drugs such as heroin or morphine in drug addicts who have agreed to be treated for their addiction. Suboxone is used in adults and children over 15 years of age, who are also receiving medical, social and psychological support.

The medicine can only be obtained by 'special' prescription. This means that because the medicine can be misused or cause addiction, it is used under stricter conditions than normal.

How is Suboxone used?

Suboxone must be used under the supervision of a doctor who has experience in the management of opioid addiction. It is recommended that the patient's liver be checked before starting treatment with Suboxone and should also be monitored regularly during treatment. In patients who have mild to moderately reduced liver function lower starting doses are recommended. 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

The tablets must never be swallowed but should be placed under the tongue and allowed to dissolve, which usually takes five to 10 minutes. The recommended starting dose is one or two tablets of Suboxone 2 mg/0.5 mg. The doctor may increase the dose depending on the patient's response but the daily dose should not be higher than 24 mg buprenorphine. Once the patient has been stabilised, the maintenance dose may be reduced gradually and eventually treatment may be stopped.

The effectiveness of Suboxone treatment depends on the patient also receiving other medical, social and psychological support.

How does Suboxone work?

Suboxone contains two active substances: buprenorphine, a partial opioid agonist (it acts like an opioid drug), and naloxone, an opioid antagonists (it counteracts the effects of opioid drugs).

Sublingual tablets containing buprenorphine alone have been available in the EU since the mid-1990's for the treatment of opioid addiction. However, buprenorphine tablets have been misused by drug addicts who dissolve the tablets and inject themselves with the resulting solution. The addition of naloxone helps prevent the misuse of the medicine. This is because, when injected, naloxone counteracts the effects of opioids, causing the patient to experience acute withdrawal symptoms.

How has Suboxone been studied?

One main study compared Suboxone with buprenorphine on its own or with placebo (a dummy treatment) in 326 heroin-dependent patients for four 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 measured.

What benefit has Suboxone shown during the studies?

Suboxone was as effective as buprenorphine on its own and more effective than placebo: 17.8% of the patients who received Suboxone had a urine sample that tested negative at the end of the study, compared with 5.8% of the patients receiving placebo. The craving score, which was between 62.4 and 65.6 before treatment, decreased at the end of the study to 29.8 with Suboxone, compared with 55.1 with placebo.

What is the risk associated with Suboxone?

The most common side effects with Suboxone (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 must not be used in patients with severe respiratory insufficiency (difficulty breathing) or severe liver problems. It must also not be used in patients with acute alcohol intoxication (excessive alcohol consumption), *delirium tremens* (a condition caused by alcohol withdrawal) or together with medicines known as opioid antagonists used for the treatment of alcohol or opioid dependence.

Why has Suboxone been approved?

The CHMP noted that the combination of an opioid analogue with an opioid antagonist is an established strategy for reducing the potential misuse of the medicine. The Committee decided that Suboxone's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Suboxone?

A risk management plan has been developed to ensure that Suboxone is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Suboxone, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Suboxone

The European Commission granted a marketing authorisation valid throughout the European Union for Suboxone on 26 September 2006.

The full EPAR for Suboxone can be searched for on the Agency's website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports For more information about treatment with Suboxone, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 10-2015.