EMA/305684/2020
EMEA/H/C/000697

Suboxone (*buprenorphine / naloxone*)

An overview of Suboxone and why it is authorised in the EU

What is Suboxone and what is it used for?

Suboxone is a medicine 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.

Suboxone is contains two active substances, buprenorphine and naloxone.

How is Suboxone used?

Suboxone is available as a film to be placed either under the tongue or on the inside of the cheek, where it will dissolve in about 5 to 10 minutes.

Suboxone must be used under the supervision of a doctor who has experience in the management of opioid addiction. The medicine can only be obtained by 'special' prescription, which means it is used under stricter conditions than normal. This medicine can itself cause addiction so this measure is required to reduce misuse.

The precise 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.

When starting treatment, Suboxone should be placed under the tongue. Once the patient is stabilised on a maintenance dose the film may also be placed inside the cheek. The recommended starting dose is 4 mg buprenorphine and 1 mg naloxone. The doctor may increase the dose depending on the patient's response but the daily dose should not exceed 24 mg buprenorphine. Once the patient has been stabilised, the maintenance dose may be reduced gradually and eventually treatment may be stopped. 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 effectiveness of Suboxone treatment depends on the patient also receiving other medical, social and psychological support.

For more further information about using Suboxone, see the package leaflet or contact your doctor or pharmacist.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

How does Suboxone work?

Suboxone contains two active substances. Buprenorphine is a partial opioid agonist which means that it acts like an opioid drug. Naloxone is an opioid antagonist; this means that it counteracts the effects of opioid drugs.

The addition of naloxone helps to discourage inappropriate use, since if the medicine is misused it leads to withdrawal symptoms..

What benefits of Suboxone have been shown in studies?

Suboxone was as effective as buprenorphine on its own and more effective than placebo (a dummy treatment) at reducing the use of opioids. In a study involving 326 heroin-dependent patients, 17.8% of patients who received Suboxone had no trace of opioids in their urine after 4 weeks, compared with 5.8% of patients receiving placebo. Patients also used a validated questionnaire to record their cravings. 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 are the risks associated with Suboxone?

The most common side effects with Suboxone (which may affect more than 1 in 10 people) are insomnia (difficulty sleeping), constipation, nausea (feeling sick), sweating, headache and withdrawal syndrome.

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.

For the full list of side effects and restrictions of Suboxone, see the package leaflet.

Why has Suboxone been authorised in the EU?

Suboxone is as effective as buprenorphine on its own at reducing the use of opioids. The European Medicines Agency 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 Agency decided that Suboxone's benefits are greater than its risks and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Suboxone have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Suboxone are continuously monitored. Side effects reported with Suboxone are carefully evaluated and any necessary action taken to protect patients.

Other information about Suboxone

Suboxone received a marketing authorisation valid throughout the EU on 26 September 2006.

Further information on Suboxone can be found on the Agency's website ema.europa.eu/medicines/human/EPAR/suboxone

This overview was last updated in 06-2020.