



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Buprenorphine Neuraxpharm (*buprenorphine*)

An overview of Buprenorphine Neuraxpharm and why it is authorised in the EU

What is Buprenorphine Neuraxpharm and what is it used for?

Buprenorphine Neuraxpharm is a medicine used to treat dependence on opioid (narcotic) drugs such as heroin or morphine. It is used in adults and adolescents aged 15 years and above who have agreed to be treated for addiction and who are also receiving medical, social and psychological support.

Buprenorphine Neuraxpharm contains the active substance buprenorphine and is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' containing the same active substance, but that it is given in a different way. The reference medicine for Buprenorphine Neuraxpharm is Subutex. Buprenorphine Neuraxpharm is available as a sublingual film (a film to be placed under the tongue), whereas Subutex is available as sublingual tablets or a solution for injection.

How is Buprenorphine Neuraxpharm used?

Buprenorphine Neuraxpharm is given as a film to be placed under the tongue once a day, where it will dissolve in about 10 to 15 minutes.

Treatment should be started by and remain under the supervision of a doctor experienced in the management of opioids dependence/addiction. It is recommended that Buprenorphine Neuraxpharm is used in combination with other interventions for opioid drug dependence.

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.

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

How does Buprenorphine Neuraxpharm work?

The active substance in Buprenorphine Neuraxpharm, buprenorphine, is a partial opioid agonist/antagonist. This means that it acts like an opioid drug but less powerfully, and it can therefore be used in a controlled way to help prevent withdrawal symptoms and reduce the urge to misuse other opioids.

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What benefits of Buprenorphine Neuraxpharm have been shown in studies?

Because buprenorphine is a widely used, well-known active substance, its effectiveness is well described in the medical literature. In addition, studies have shown that giving Buprenorphine Neuraxpharm produces similar levels of the active substance in the body as giving Subutex.

What are the risks associated with Buprenorphine Neuraxpharm?

For the full list of side effects and restrictions with Buprenorphine Neuraxpharm, see the package leaflet.

The most common side effects with Buprenorphine Neuraxpharm (which may affect more than 1 in 10 people) include symptoms of drug withdrawal, such as insomnia (difficulty sleeping), headache, nausea (feeling sick), hyperhidrosis (excessive sweating) and pain.

Buprenorphine Neuraxpharm must not be used in patients with severe respiratory insufficiency (inability to breathe properly) or severe liver problems, and in patients who are intoxicated with alcohol or who are experiencing alcohol withdrawal symptoms.

Why is Buprenorphine Neuraxpharm authorised in the EU?

The European Medicines Agency considered that the benefits and risks of the active substance, buprenorphine, are well known from the medical literature. Studies have shown that Buprenorphine Neuraxpharm produces sufficient levels of the active substance in people given the medicine. The Agency therefore concluded that the medicine's benefits are greater than its risks and that it can be authorised for use in the EU.

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

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

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

Other information about Buprenorphine Neuraxpharm

Buprenorphine Neuraxpharm received a marketing authorisation valid throughout the EU on 19 December 2024.

Further information on Buprenorphine Neuraxpharm can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Buprenorphine-Neuraxpharm.

This overview was last updated in 12-2024.