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Buvidal (*buprenorphine*)

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

What is Buvidal and what is it used for?

Buvidal is a medicine used to treat dependence on opioid (narcotic) drugs such as heroin or morphine.

Buvidal is used in adults and adolescents aged over 16 years who are also receiving medical, social and psychological support.

Buvidal 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 Buvidal is given in a different way.

The reference medicine for Buvidal is Subutex. While Subutex is available as sublingual tablets (tablets to be placed under the tongue), Buvidal is available as a solution for injection under the skin.

How is Buvidal used?

Buvidal is given as an injection under the skin, either once a week or once a month.

It can only be obtained with a prescription and can only be given by a healthcare professional. Patients cannot take the medicine home or inject it themselves.

The first dose of Buvidal is given when the patient shows clear signs of withdrawal. For patients dependent on short-acting opioids (e.g. morphine or heroin), the first dose is given at least 6 hours after the patient last used an opioid. For patients dependent on long-acting opioids (e.g. methadone), the dose of methadone is reduced to below 30 mg per day before starting Buvidal. The first dose of Buvidal is given at least 24 hours after the patient last used methadone.

Patients who have never taken buprenorphine before should be given a 4 mg buprenorphine tablet and be monitored for one hour before being given Buvidal, to make sure they tolerate the medicine. These patients should be started on weekly doses of Buvidal before moving to monthly injections. Patients who have taken buprenorphine before may be switched directly to weekly or monthly Buvidal injections.

The dose of Buvidal can be adjusted and patients can be switched between weekly and monthly injections according to the patient's need and the judgement of the treating doctor.

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

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

How does Buvidal work?

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

What benefits of Buvidal have been shown in studies?

A study involving 428 patients with opioid dependence showed that Buvidal was effective at reducing patients' intake of opioid drugs. In this study, Buvidal was compared with sublingual tablets containing buprenorphine and another medicine, naloxone (which is used to prevent misuse). The main measure of effectiveness was based on the number of urine samples that tested negative for opioids. During the 25 weeks of treatment, 35% of patients given Buvidal had a negative urine test, compared with 28% of patients taking the comparator tablets.

What are the risks associated with Buvidal?

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

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

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

Why is Buvidal authorised in the EU?

The European Medicines Agency concluded that Buvidal was at least as effective as buprenorphine tablets at treating opioid dependence. Weekly or monthly injections with Buvidal would offer an additional option for managing the condition. Although information on the long-term safety of the new formulation was lacking, the Agency's view was that the benefit of Buvidal outweighs the identified risk and it can be authorised for use in the EU.

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

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

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

Other information about Buvidal

Buvidal received a marketing authorisation valid throughout the EU on 20 November 2018.

Further information on Buvidal can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Buvidal. Information on the reference medicine can also be found on the Agency's website.

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