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Withdrawal of application to change the marketing authorisation for Buvidal (buprenorphine)

Camurus AB withdrew its application for the use of Buvidal to treat chronic (long-term) pain in people with dependence on opioids.

The company withdrew the application on 13 February 2023.

What is Buvidal and what is it used for?

Buvidal is a medicine used to treat dependence on opioids such as heroin or morphine. It is used in adults and adolescents aged 16 years and above 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.

Buvidal has been authorised in the EU since November 2018.

Further information on Buvidal's current uses can be found on the Agency's website: ema.europa.eu/en/medicines/human/EPAR/buvidal.

What change had the company applied for?

The company applied to extend the use of Buvidal to treat moderate to severe chronic pain in patients aged 16 years and over with opioid dependence.

How does Buvidal work?

The active substance in Buvidal, buprenorphine, is a partial opioid agonist. The medicine acts on opioid receptors (targets) in the brain and spinal cord, which are involved in feelings of pleasure and pain relief. By acting on these receptors, Buvidal works like an opioid drug, but less powerfully. This means it can be used in a controlled way to help prevent withdrawal symptoms in patients with opioid dependence and reduce their urge to misuse other opioids.

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In the treatment of chronic pain, Buvidal works in the same way as it does in its existing indication.

What did the company present to support its application?

The company presented the results of a study involving 611 patients who had been taking opioids for at least 3 months to treat chronic lower back pain and who experienced mild withdrawal symptoms when the opioid dose was reduced.

Patients received Buvidal for 10 weeks; after this time, 330 patients who had reached a stable and effective dose of the medicine either continued receiving Buvidal or were given placebo (a dummy treatment). Other pain medicines could also be used in limited amounts if the pain increased. The main measure of effectiveness was a decrease in the average pain intensity score reported by patients.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and had prepared questions for the company. After the Agency had assessed the company's responses to the questions, there were still some unresolved issues.

What did the Agency recommend at that time?

Based on the review of the information and the company's response to the Agency's questions, at the time of the withdrawal, the Agency had concerns about changing Buvidal's marketing authorisation to add treatment of chronic pain in patients with opioid dependence.

The Agency had concerns about the way the study had been carried out. Data from two study sites had to be excluded from the final analysis because of concerns about the data's reliability, and a number of study sites had not been inspected or audited.

In addition, the company had not adequately shown that the study design and patient population were appropriate to support the intended use. The Agency also had concerns about the clinical relevance of the difference seen between Buvidal and placebo.

Therefore, at the time of the withdrawal, the Agency's opinion was that the company had not provided enough information to support the application for a change to the marketing authorisation of Buvidal.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of application, the company stated that the withdrawal was based on the company's assessment of EMA's request for further data to support approval in the proposed indication.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using Buvidal.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.

What is happening with Buvidal for the treatment of dependence on opioids?

There are no consequences on the use of Buvidal in its authorised use.