20 September 2018
EMA/618608/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Buvidal

buprenorphine

On 20 September 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Buvidal, intended for the treatment of opioid dependence. The applicant for this medicinal product is Camurus AB.

Buvidal will be available as a prolonged-release solution for injection (8, 16, 24, 32, 64, 96 and 128 mg). The active substance of Buvidal is buprenorphine, an opioid partial agonist/antagonist (ATC code: N07BC01).

The benefit with Buvidal is that it can substitute for opioids during addiction treatment. The most common side effects are headache, nausea, hyperhidrosis and insomnia.

Buvidal is a hybrid medicine of Subutex, which has been authorised in the EU since 1998. Buvidal contains the same active substance as Subutex, but differs in strength and route of delivery.

The full indication is: “Treatment of opioid dependence within a framework of medical, social and psychological treatment. Treatment is intended for use in adults and adolescents aged 16 years or over.”

It is proposed that Buvidal be prescribed by physicians experienced in the treatment of opioid addiction.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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