14 September 2017
EMA/CHMP/535541/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zubsolv

buprenorphine / naloxone

On 14 September 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zubsolv, intended for the treatment of opioid dependence. The applicant for this medicinal product is Mundipharma Corporation Limited.

Zubsolv contains the active substances buprenorphine and naloxone and will be available as tablets for sublingual use (0.7 mg / 0.18 mg, 1.4 mg / 0.36 mg, 2.9 mg / 0.71 mg, 5.7 mg / 1.4 mg, 8.6 mg / 2.1 mg and 11.4 mg / 2.9 mg). Buprenorphine and naloxone are used in addictive disorders (ATC code: N07BC51) and act as opioid agonist and opioid receptor antagonist, respectively.

The benefit of Zubsolv is substitution of opioids during addiction treatment. The most common side effects are constipation, nausea, insomnia and headache.

The full indication is: "Substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. The intention of the naloxone component is to deter intravenous misuse. Treatment is intended for use in adults and adolescents over 15 years of age who have agreed to be treated for addiction."

It is proposed that Zubsolv be prescribed by physicians experienced in the treatment of opioid dependence.

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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