17 October 2024
EMA/CHMP/112129/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Buprenorphine Neuraxpharm

buprenorphine

On 17 October 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Buprenorphine Neuraxpharm, intended for the substitution treatment of opioid dependence.

The applicant for this medicinal product is Neuraxpharm Pharmaceuticals S.L.

Buprenorphine Neuraxpharm will be available as 0.4 mg, 4 mg, 6 mg and 8 mg sublingual films. The active substance of Buprenorphine Neuraxpharm is buprenorphine, a drug used in opioid dependence (ATC code: N07BC01). Buprenorphine is a partial opioid agonist/antagonist.

The benefit with buprenorphine Neuraxpharm is that it can be used as a substitute for opioids during addiction treatment. The most common side effects with buprenorphine Neuraxpharm are headache, nausea, hyperhidrosis, insomnia, abdominal pain, drug withdrawal syndrome.

Buprenorphine Neuraxpharm is a hybrid medicine[2] of Subutex, which has been authorised in the EU since 1995. Buprenorphine Neuraxpharm contains the same active substance as Subutex, but the formulation differs. Buprenorphine Neuraxpharm will be available as sublingual films, whereas Subutex is available as a prolonged-release solution for injection or as sublingual tablets.

The full indication is:

- Substitution treatment of opioid drug dependence, within a comprehensive therapeutic monitoring framework of medical, social and psychological treatment.
- Treatment is intended for use in adults and adolescents 15 years of age and older, who have agreed to be treated for addiction.

Treatment with buprenorphine Neuraxpharm should be prescribed and supervised by a doctor experienced in the treatment of opiate dependence/addiction. Buprenorphine Neuraxpharm is subject to special and restricted medical prescription.

[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
[2] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

© European Medicines Agency, 2024. Reproduction is authorised provided the source is acknowledged.

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.