26 April 2019
EMA/CHMP/215656/2019
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Sixmo

## buprenorphine

On 26 April 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Sixmo, intended for the treatment of opioid dependence. The applicant for this medicinal product is L. Molteni & C. dei Fratelli Alitti Società di Esercizio S.p.A.

Sixmo will be available as an implant (74.2 mg). The active substance of Sixmo is buprenorphine, an opioid partial agonist/antagonist (ATC code: N07BC01).

The benefit with Sixmo are its ability to substitute for opioids during addiction treatment. The most common side effects are implant-related adverse events, headache, constipation and insomnia.

The full indication is: "Sixmo is indicated for substitution treatment for opioid dependence in clinically stable adult patients who require no more than 8 mg/day of sublingual buprenorphine, within a framework of medical, social and psychological treatment." It is proposed that Sixmo 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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