14 November 2019
EMA/CHMP/569229/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Sunosi

solriamfetol

On 14 November 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 Sunosi, intended for the treatment of excessive daytime sleepiness in narcolepsy and obstructive sleep apnoea. The applicant for this medicinal product is Jazz Pharmaceuticals Ireland Limited.

Sunosi will be available as 75 mg and 150 mg film-coated tablets. The active substance of Sunosi is solriamfetol, a psychoanaleptic (ATC code: N06BA14) which is a dopamine and norepinephrine reuptake inhibitor.

The benefits with Sunosi are its ability to improve patients' wakefulness and to reduce their daytime sleepiness. The most common side effects are headache and nausea.

The full indication is:

"Sunosi is indicated to improve wakefulness and reduce excessive daytime sleepiness in adult patients with narcolepsy (with or without cataplexy).

Sunosi is indicated to improve wakefulness and reduce excessive daytime sleepiness (EDS) in adult patients with obstructive sleep apnoea (OSA) whose EDS has not been satisfactorily treated by primary OSA therapy, such as continuous positive airway pressure (CPAP)."

It is proposed that Sunosi be prescribed by physicians experienced in the treatment of sleep disorders.

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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