

**SUNOSI
(solriamfetol)****RATIONALE FOR INCLUSION IN PA PROGRAM****Background**

Sunosi (solriamfetol) is a selective dopamine and norepinephrine reuptake inhibitor (DNRI) used to improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA). Sunosi's efficacy is thought to be mediated through its activity as a dopamine and norepinephrine reuptake inhibitor (1).

Regulatory Status

FDA-approved indication: Sunosi is a dopamine and norepinephrine reuptake inhibitor (DNRI) that is indicated to improve wakefulness in patients with excessive daytime sleepiness (EDS) associated with narcolepsy or obstructive sleep apnea (OSA) (1).

Limitations of use: Sunosi is not indicated to treat underlying airway obstruction in OSA. Underlying airway obstruction must be treated (i.e., with continuous positive airway pressure (CPAP)) for at least one month before initiation of Sunosi for excessive daytime sleepiness. Sunosi is an adjunct treatment for underlying airway obstruction and should not be used in substitution to current treatment (1).

Sunosi increases systolic blood pressure, diastolic blood pressure and heart rate in a dose-dependent manner. Chronic elevations in blood pressure increase the risk of major cardiovascular events including stroke, heart attack, and cardiovascular death. Patients with narcolepsy and OSA have multiple risk factors for major cardiovascular events including hypertension, diabetes, hyperlipidemia and high body mass index (BMI). Blood pressure should be monitored regularly during treatment. New-onset hypertension and exacerbations of previously existing hypertension should be treated. Sunosi should be used cautiously with other drugs that can increase blood pressure and heart rate (1).

Psychiatric adverse reactions including anxiety, irritability and insomnia may occur with Sunosi treatment. However, Sunosi has not been evaluated in bipolar disorders or in patients with psychosis, so caution should be exercised with use in this population. Dose reduction or discontinuation of Sunosi should be considered if exacerbations of psychiatric symptoms occur (1).



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SUNOSI (solriamfetol)

Sunosi should not be administered with monoamine oxidase inhibitors (MAOIs) or within 14 days of discontinuation of MAOI because of the risk of hypertensive reaction (1).

Physicians should evaluate patients carefully for a recent history of drug abuse, stimulant, or alcohol abuse. Physicians should follow such patients closely to observe for signs of misuse and abuse (1).

Sunosi is not recommended for use in patients with end stage renal disease (ESRD) (1).

The safety and effectiveness of Sunosi in pediatric patients less than 18 years of age have not been established (1).

Summary

Sunosi (solriamfetol) is a selective dopamine and norepinephrine reuptake inhibitor (DNRI) used to improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA). Sunosi's efficacy is thought to be mediated through its activity as a dopamine and norepinephrine reuptake inhibitor. The safety and effectiveness of Sunosi in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Sunosi while maintaining optimal therapeutic outcomes.

References

1. Sunosi [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; June 2023.