Wake-Up Call Questionnaire

These 4 questions can help you evaluate how well your patients are doing on their current EDS treatment and discuss whether SUNOSI may be right for them. At each visit, ask your patients with OSA or narcolepsy:

1. Does your current medication help you feel awake and alert throughout the day?

2. Do you need to redose your current medication in the afternoon?

3. Are you experiencing any of these issues?

- ☐ Struggling to stay focused and remember things throughout the day
- ☐ Strained relationships with family, friends, and/or coworkers
- ☐ Too tired to engage with family and friends after work
- ☐ Falling asleep in public places or while relaxing (watching TV, reading, etc)
- ☐ Worrying about falling asleep while driving
- ☐ Regularly avoiding activities due to tiredness
- ☐ Feeling tired regardless of nighttime hours spent sleeping
- ☐ None of the above

4. [For patients with OSA] Do you struggle to stay awake during the day despite using a CPAP at night?

CPAP=continuous positive airway pressure; EDS=excessive daytime sleepiness; OSA=obstructive sleep apnea.

INDICATION AND IMPORTANT SAFETY INFORMATION FOR SUNOSI (solriamfetol)

INDICATION

SUNOSI is indicated to improve wakefulness in adults with excessive daytime sleepiness (EDS) associated with narcolepsy or obstructive sleep apnea (OSA).

LIMITATIONS OF USE

SUNOSI is not indicated to treat the underlying obstruction in OSA. Ensure that the underlying airway obstruction is treated (e.g., with continuous positive airway pressure (CPAP)) for at least one month prior to initiating SUNOSI. SUNOSI is not a substitute for these modalities, and the treatment of the underlying airway obstruction should be continued.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

SUNOSI is contraindicated in patients receiving concomitant treatment with monoamine oxidase inhibitors (MAOIs), or within 14 days following discontinuation of an MAOI, because of the risk of hypertensive reaction.

Please see additional Important Safety Information on reverse and full Prescribing Information.

WARNINGS AND PRECAUTIONS

Blood Pressure and Heart Rate Increases

SUNOSI increases systolic blood pressure, diastolic blood pressure, and heart rate in a dose-dependent fashion.

Epidemiological data show that chronic elevations in blood pressure increase the risk of major adverse cardiovascular events (MACE), including stroke, heart attack, and cardiovascular death. The magnitude of the increase in absolute risk is dependent on the increase in blood pressure and the underlying risk of MACE in the population being treated. Many patients with narcolepsy and OSA have multiple risk factors for MACE, including hypertension, diabetes, hyperlipidemia, and high body mass index (BMI).

Assess blood pressure and control hypertension before initiating treatment with SUNOSI. Monitor blood pressure regularly during treatment and treat new-onset hypertension and exacerbations of pre-existing hypertension.

SUNOSI® (solriamfetol) CIV
75, 150 mg tablets

IMPORTANT SAFETY INFORMATION (CONT'D)

Blood Pressure and Heart Rate Increases

Exercise caution when treating patients at higher risk of MACE, particularly patients with known cardiovascular and cerebrovascular disease, pre-existing hypertension, and patients with advanced age. Use caution with other drugs that increase blood pressure and heart rate.

Periodically reassess the need for continued treatment with SUNOSI. If a patient experiences increases in blood pressure or heart rate that cannot be managed with dose reduction of SUNOSI or other appropriate medical intervention, consider discontinuation of SUNOSI.

Patients with moderate or severe renal impairment could be at a higher risk of increases in blood pressure and heart rate because of the prolonged half-life of SUNOSI.

Psychiatric Symptoms

Psychiatric adverse reactions have been observed in clinical trials with SUNOSI, including anxiety, insomnia, and irritability.

Exercise caution when treating patients with SUNOSI who have a history of psychosis or bipolar disorders, as SUNOSI has not been evaluated in these patients.

Patients with moderate or severe renal impairment may be at a higher risk of psychiatric symptoms because of the prolonged half-life of SUNOSI.

Observe SUNOSI patients for the possible emergence or exacerbation of psychiatric symptoms. Consider dose reduction or discontinuation of SUNOSI if psychiatric symptoms develop.

MOST COMMON ADVERSE REACTIONS

The most common adverse reactions (incidence ≥5%) reported more frequently with the use of SUNOSI than placebo in either narcolepsy or OSA were headache, nausea, decreased appetite, anxiety, and insomnia.

Dose-Dependent Adverse Reactions

In the 12-week placebo-controlled clinical trials that compared doses of 37.5 mg, 75 mg, and 150 mg/day of SUNOSI to placebo, the following adverse reactions were dose-related: headache, nausea, decreased appetite, anxiety, diarrhea, and dry mouth.

DRUG INTERACTIONS

Do not administer SUNOSI concomitantly with MAOIs or within 14 days after discontinuing MAOI treatment. Concomitant use of MAOIs and noradrenergic drugs may increase the risk of a hypertensive reaction. Potential outcomes include death, stroke, myocardial infarction, aortic dissection, ophthalmological complications, eclampsia, pulmonary edema, and renal failure.

Concomitant use of SUNOSI with other drugs that increase blood pressure and/or heart rate has not been evaluated, and combinations should be used with caution.

Dopaminergic drugs that increase levels of dopamine or that bind directly to dopamine receptors might result in pharmacodynamic interactions with SUNOSI. Interactions with dopaminergic drugs have not been evaluated with SUNOSI. Use caution when concomitantly administering dopaminergic drugs with SUNOSI.

USE IN SPECIFIC POPULATIONS

Renal Impairment

Dosage adjustment is not required for patients with mild renal impairment (eGFR 60-89 mL/min/1.73 m^2). Dosage adjustment is recommended for patients with moderate to severe renal impairment (eGFR 15-59 mL/min/1.73 m^2). SUNOSI is not recommended for patients with end stage renal disease (eGFR <15 mL/min/1.73 m^2).

ABUSE

SUNOSI contains solriamfetol, a Schedule IV controlled substance. Carefully evaluate patients for a recent history of drug abuse, especially those with a history of stimulant or alcohol abuse, and follow such patients closely, observing them for signs of misuse or abuse of SUNOSI (e.g., drug-seeking behavior).

Please see additional Important Safety Information on reverse and full Prescribing Information.

SUN HCP ISI 05/2022

Reference:

1. What Is Excessive Sleepiness. Accessed April 5, 2023. Sleepfoundation.org/excessive-sleepiness

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