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SUNOSI is all about**

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SUNOSI
(solriamfetol) (IV)
75, 150 mg tablets

When your adult patients with obstructive sleep apnea (OSA) or narcolepsy are struggling with excessive daytime sleepiness (EDS),

Once-daily SUNOSI is the first and only WPA proven to improve wakefulness through 9 HOURS^{1,2*†}



*As seen at week 12.

†The 75 mg dose did not show a statistically significant improvement for patients with narcolepsy-associated EDS.

WPA=wake-promoting agent.

INDICATIONS AND USAGE

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

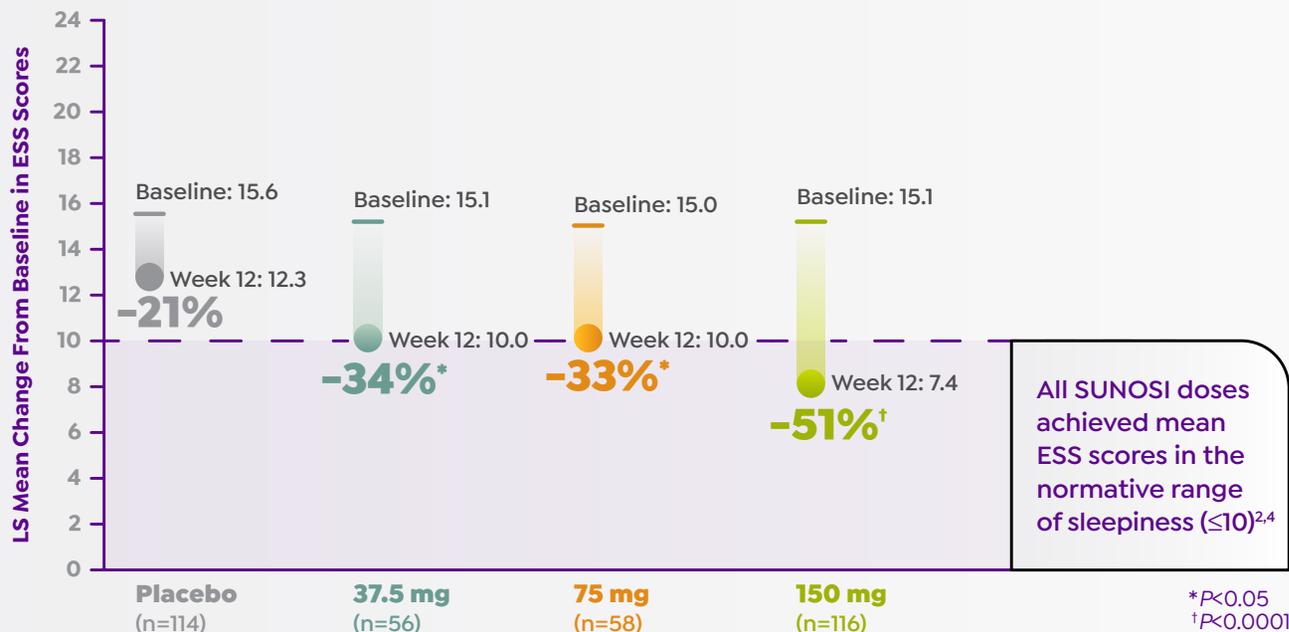
CONTRAINDICATIONS

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.



Significant reductions in daytime sleepiness

Across doses, SUNOSI improved patient-reported sleepiness at week 12, as measured by the ESS^{2,3}



ESS=Epworth Sleepiness Scale.

ESS definition >

Study design >

IMPORTANT SAFETY INFORMATION (CONT'D)

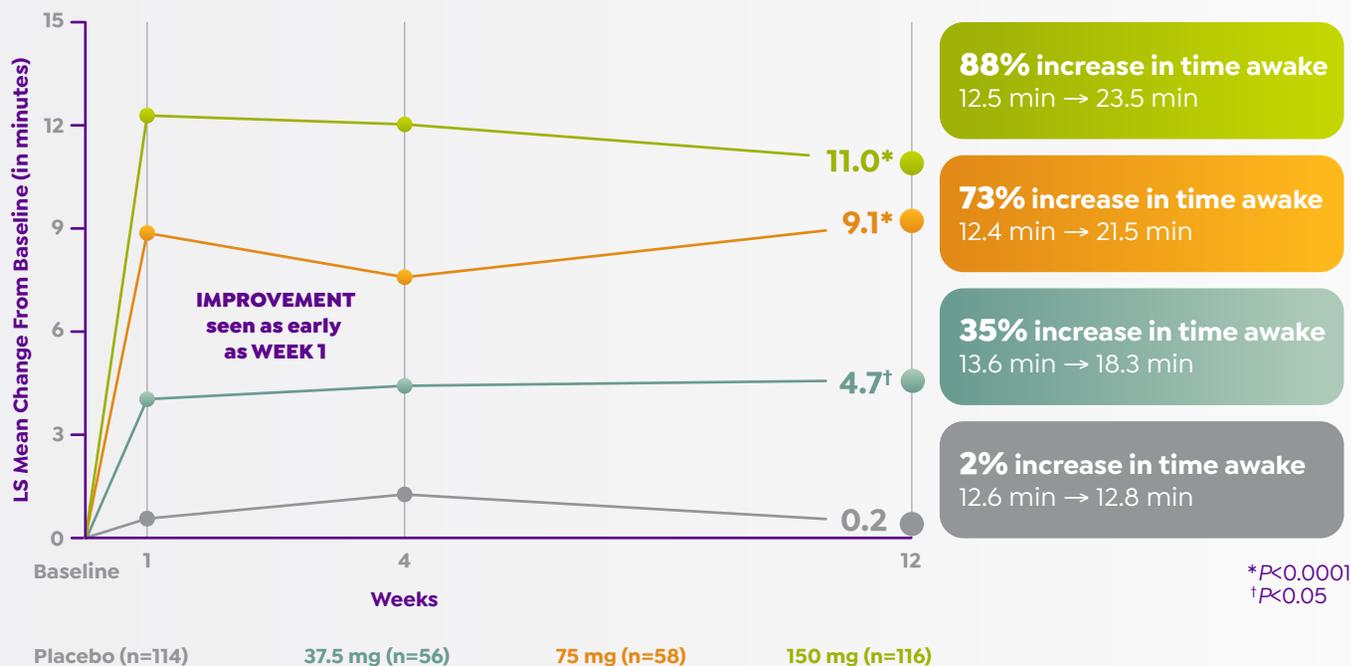
WARNINGS AND PRECAUTIONS

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).

Ability to stay awake significantly improved

Across doses, SUNOSI provided more minutes of wakefulness at week 12, as measured by the MWT^{2,3}



MWT=Maintenance of Wakefulness Test.

- Improvement seen as early as week 1^{2,3}
- At week 12, there was a significant increase from baseline in the average time participants were able to remain awake during the 40-minute MWT trials^{2,3}

MWT definition >

Study design >

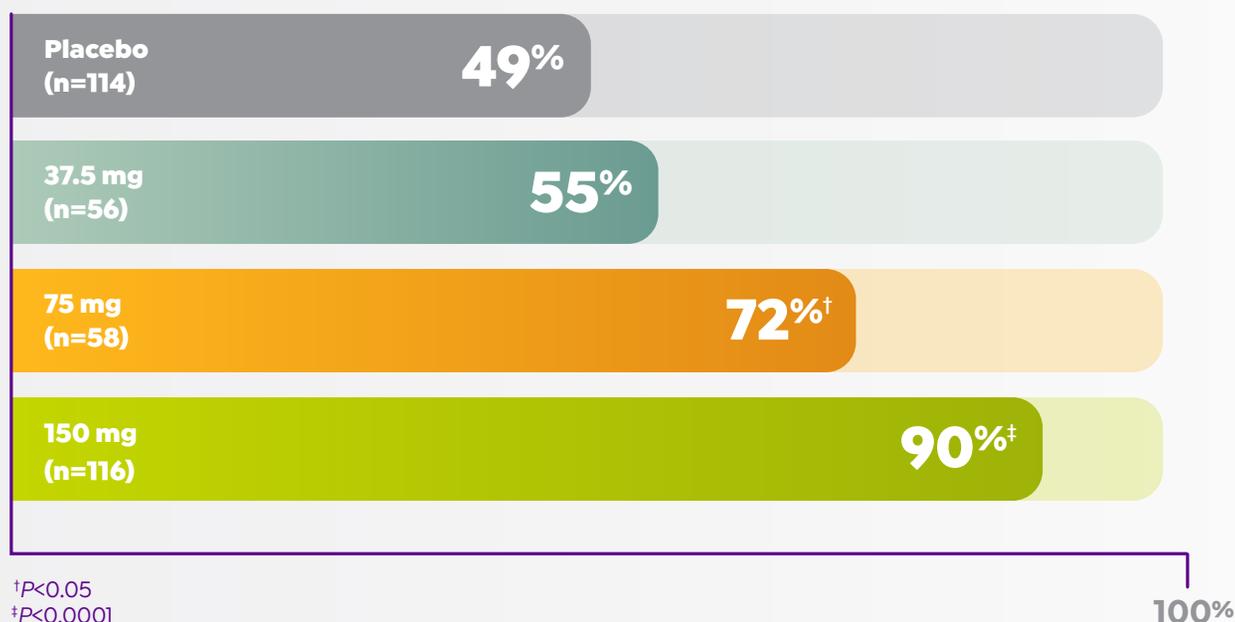
IMPORTANT SAFETY INFORMATION (CONT'D)

Blood Pressure and Heart Rate Increases (Cont'd)

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. 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.

Demonstrated improvement in patient-reported symptoms

Across doses, SUNOSI improved symptoms at week 12, as measured by the PGIC^{3*}



[†]P<0.05
[‡]P<0.0001

PGIC=Patient Global Impression of Change.

*The percentage of patients improved on the PGIC includes those who reported very much, much, and minimal improvement.³

[PGIC definition >](#)

[Study design >](#)

IMPORTANT SAFETY INFORMATION (CONT'D)

Blood Pressure and Heart Rate Increases (Cont'd)

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.

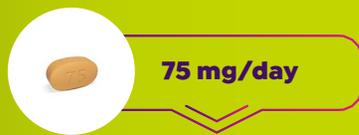
Patients with moderate or severe renal impairment could be at a higher risk of increases in blood pressure and heart rate because of the prolonged half-life of SUNOSI.

Once-daily dosing can be optimized for the right balance of efficacy and tolerability

START patients with OSA here



After ≥3 days, titrate up as needed



After ≥3 days, titrate up as needed



ALL DOSES improved wakefulness through **9 HOURS** at week 12

*The 75 mg tablet is scored and can be broken in half for patients starting at the 37.5 mg dose.²

Before initiating treatment with SUNOSI, assess blood pressure and ensure hypertension is controlled.²

In the 12-week placebo-controlled studies that compared SUNOSI 37.5 mg, 75 mg, and 150 mg to placebo, the following adverse reactions were dose-related: headache, nausea, decreased appetite, anxiety, diarrhea, and dry mouth.²

The maximum recommended dose is 150 mg once daily.²

Important dosing instructions to share with patients



SUNOSI should be taken once daily upon awakening— at least 9 hours before planned bedtime—to avoid potential interference with sleep²



For many patients, **SUNOSI worked in as little as 1 hour after dosing, as seen at week 12²**



SUNOSI can be taken with or without food— no timing with meals necessary²



[Download the SUNOSI Dosing Card](#) >

IMPORTANT SAFETY INFORMATION (CONT'D)

Psychiatric Symptoms

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

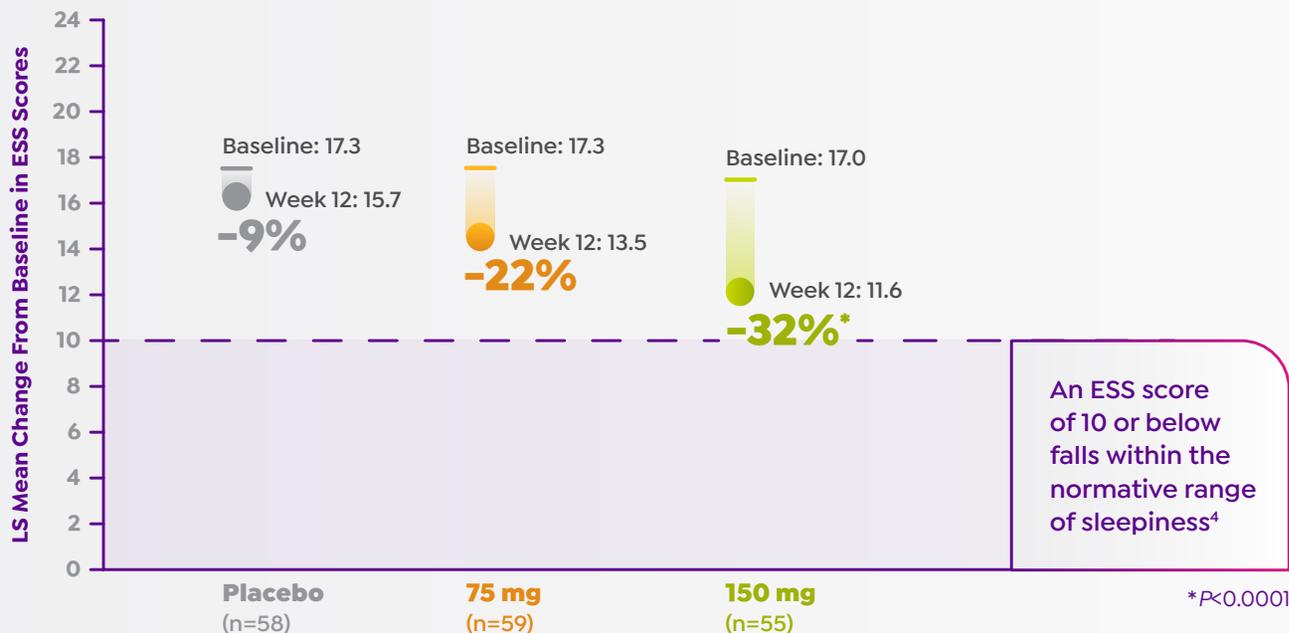
Exercise caution when treating patients with SUNOSI who have a history of psychosis or bipolar disorders, as SUNOSI has not been evaluated in these patients.

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.

Demonstrated reductions in daytime sleepiness

SUNOSI 150 mg significantly improved patient-reported sleepiness at week 12, as measured by the ESS^{2,5}



ESS=Epworth Sleepiness Scale.

Patients randomized to 75 mg showed a trend toward improvement; however, this change was not statistically significant.²

[ESS definition >](#)

[Study design >](#)

IMPORTANT SAFETY INFORMATION (CONT'D)

MOST COMMON ADVERSE REACTIONS

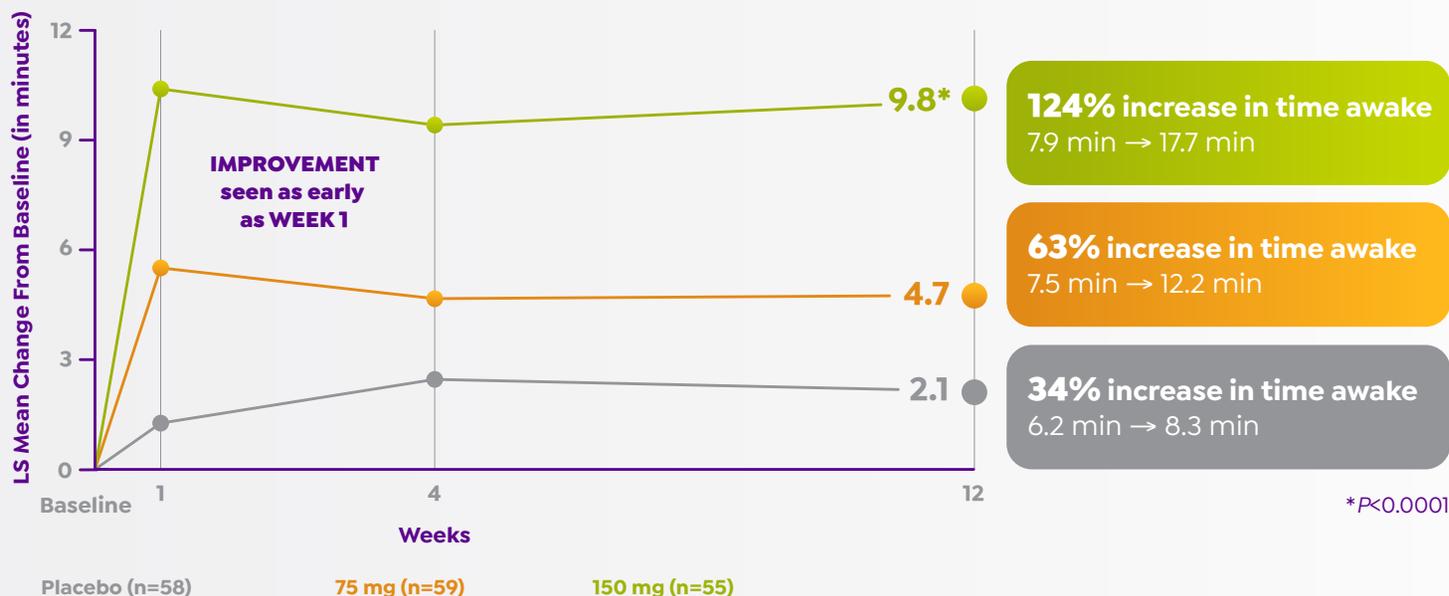
The most common adverse reactions (incidence $\geq 5\%$) reported more frequently with the use of SUNOSI than placebo in either narcolepsy or OSA were headache, nausea, decreased appetite, anxiety, and insomnia.

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.

Demonstrated improvements in ability to stay awake

SUNOSI 150 mg provided significantly more minutes of wakefulness at week 12, as measured by the MWT^{2,5}



MWT=Maintenance of Wakefulness Test.

- Improvement seen as early as week 1^{2,5}
- At week 12, there was an increase from baseline in the average time participants were able to remain awake during the 40-minute MWT trials^{2,5}
- Patients randomized to 75 mg showed a trend toward improvement; however, this change was not statistically significant²

MWT definition >

Study design >

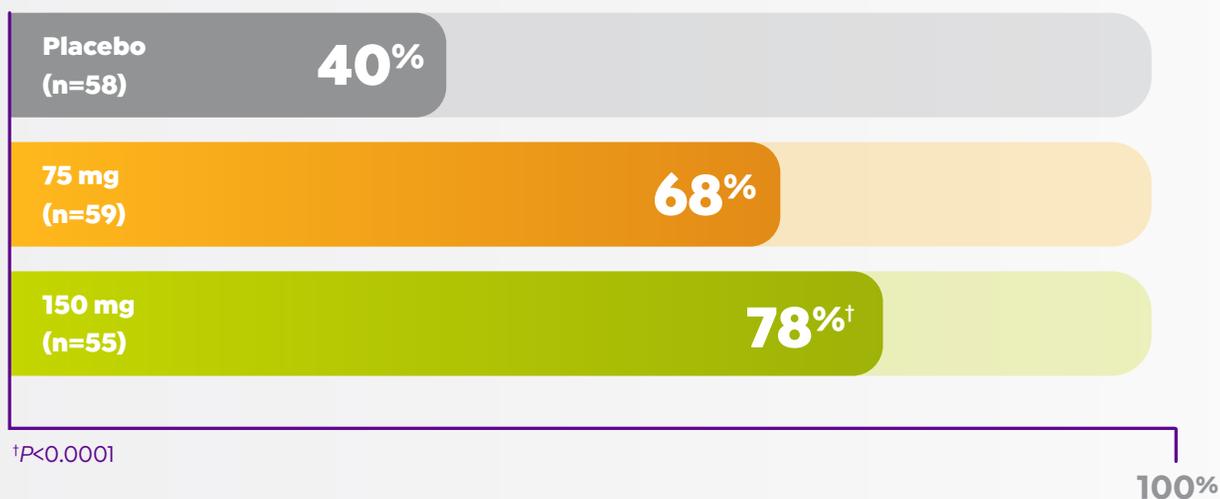
IMPORTANT SAFETY INFORMATION (CONT'D)

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.

Demonstrated improvement in patient-reported symptoms

SUNOSI 150 mg significantly improved symptoms at week 12, as measured by the PGIC^{5*}



PGIC=Patient Global Impression of Change.

*The percentage of patients improved on the PGIC includes those who reported very much, much, and minimal improvement.⁵

Patients randomized to 75 mg showed a trend toward improvement; however, this change was not statistically significant.²

[PGIC definition >](#)

[Study design >](#)

IMPORTANT SAFETY INFORMATION (CONT'D)

DRUG INTERACTIONS (CONT'D)

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.

Once-daily dosing can be optimized for the right balance of efficacy and tolerability

START patients with **NARCOLEPSY** here



75 mg/day

After ≥3 days, titrate up as needed



150 mg/day

SUNOSI 150 mg improved wakefulness through **9 HOURS** at week 12

*The 75 mg dose did not show improvement at 1 hour for patients with narcolepsy-associated EDS.²

Before initiating treatment with SUNOSI, assess blood pressure and ensure hypertension is controlled.²

In the 12-week placebo-controlled studies that compared SUNOSI 37.5 mg, 75 mg, and 150 mg to placebo, the following adverse reactions were dose-related: headache, nausea, decreased appetite, anxiety, diarrhea, and dry mouth.²

The maximum recommended dose is 150 mg once daily.²

Important dosing instructions to share with patients



SUNOSI should be taken once daily upon awakening— at least 9 hours before planned bedtime—to avoid potential interference with sleep²



For many patients, **SUNOSI worked in as little as 1 hour after dosing, as seen at week 12^{2*}**



SUNOSI can be taken with or without food— no timing with meals necessary²



[Download the SUNOSI Dosing Card](#) >

IMPORTANT SAFETY INFORMATION (CONT'D)

USE IN SPECIFIC POPULATIONS

Renal Impairment

Dosage adjustment is not required for patients with mild renal impairment (eGFR 60–89 mL/min/1.73 m²). Dosage adjustment is recommended for patients with moderate to severe renal impairment (eGFR 15–59 mL/min/1.73 m²). SUNOSI is not recommended for patients with end stage renal disease (eGFR <15 mL/min/1.73 m²).

SUNOSI has a well-established safety and tolerability profile

Most common adverse reactions²

The most common adverse reactions (≥5% and greater than placebo) reported more frequently with SUNOSI were headache, nausea, decreased appetite, anxiety, and insomnia.

Dose-dependent adverse reactions ≥2% in patients treated with SUNOSI and greater than placebo in pooled, 12-week, placebo-controlled studies²

	Placebo N=226 (%)	SUNOSI 37.5 mg N=58* (%)	SUNOSI 75 mg N=120 (%)	SUNOSI 150 mg N=218 (%)
Headache [†]	8	7	9	13
Nausea [‡]	5	7	5	9
Decreased appetite	1	2	7	8
Anxiety	1	2	3	7
Dry mouth	2	2	3	4
Diarrhea	2	2	4	5

*In OSA only.

[†]"Headache" includes headache, tension headache, and head discomfort.

[‡]"Nausea" includes nausea and vomiting.

Discontinuation due to adverse reactions in the 12-week studies²

SUNOSI (all doses; N=396)	Placebo (N=226)
3% (n=11)	<1% (n=1)

The adverse reactions resulting in discontinuation that occurred in more than 1 SUNOSI-treated patient and at a higher rate than placebo were anxiety, palpitations, and restlessness (each 2/396; <1%).

SUNOSI has a low potential for abuse and low risk of dependence



SUNOSI is a Schedule IV drug with a low risk of abuse^{2,6}

- The abuse potential of SUNOSI was shown to be similar to or lower than that of the Schedule IV stimulant phentermine—even at doses 8 times the maximum recommended daily dose²
- Physicians should carefully evaluate patients for a 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 SUNOSI²



Patients on SUNOSI showed no evidence of tolerance, dependence, or withdrawal^{2,7}

- In clinical studies, efficacy was seen as early as week 1 and was consistent at week 12, suggesting that tolerance to SUNOSI did not develop^{2,7}
- After at least 6 months of treatment, there was no evidence that abrupt discontinuation of SUNOSI resulted in adverse events suggestive of physical dependence or withdrawal²

IMPORTANT SAFETY INFORMATION (CONT'D)

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).

Support is available to help your patients get started on SUNOSI



With the SUNOSI Savings Card, eligible patients can save on their SUNOSI prescription

[Download >](#)



SUNOSI samples can help get your patients to the right dose

[Request >](#)



Free vouchers for patients considering SUNOSI

[Download >](#)

>80%

of commercial insured lives across the nation have access to SUNOSI⁸

[Learn more about coverage for SUNOSI >](#)

Choose **SUNOSI** as part of a comprehensive approach to managing EDS in patients with OSA or narcolepsy



At week 12, SUNOSI 150 mg **improved wakefulness through 9 HOURS**^{2*}



Up to 51% less daytime sleepiness for patients with OSA^{2†}

- Change from baseline to week 12, as measured by the Epworth Sleepiness Scale (15.1 points to 7.4 points); vs 21% with placebo



A well-established safety and tolerability profile²



>80% of commercial insured lives across the nation have access to SUNOSI⁸

*The 75 mg dose did not show a statistically significant improvement for patients with narcolepsy-associated EDS.²

†As seen with SUNOSI 150 mg in a 12-week, randomized, multicenter, double-blind, placebo-controlled, parallel-group study in adult patients with OSA (N=459).^{2,3}

References >

INDICATIONS AND USAGE

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

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SUNOSI was extensively studied using 3 key clinical measures



Level of sleepiness, as measured by the Epworth Sleepiness Scale (ESS)⁴

- A validated, patient-reported assessment in which respondents rate their recent likelihood of falling asleep (on a scale of 0 to 3) during 8 daily activities
- A score of 10 or below falls within the normative range of sleepiness

[ESS data in OSA >](#)

[ESS data in narcolepsy >](#)



Ability to stay awake, as measured by the Maintenance of Wakefulness Test (MWT)^{2,9}

- An objective evaluation that measures the ability to stay awake in a darkened, quiet environment during 5 separate 40-minute trials over the course of 1 day
- In the SUNOSI 12-week studies, the primary MWT analysis was the average of sleep latencies (time to sleep onset) from the first 4 of 5 MWT trials

[MWT data in OSA >](#)

[MWT data in narcolepsy >](#)



Patient-reported improvement, as measured by the Patient Global Impression of Change (PGIC) scale²

- The PGIC is a 7-point scale ranging from “very much improved” to “very much worse” that assesses a patient’s reported change in symptoms since the start of the study

[PGIC data in OSA >](#)

[PGIC data in narcolepsy >](#)

TONES 3 study design: EDS in OSA

TONES 3: EXCESSIVE DAYTIME SLEEPINESS (EDS) IN OSA ^{2,3}	
Study Design	12-week, randomized, multicenter, double-blind, placebo-controlled, parallel-group study in adult patients with OSA (N=459)
Study Arms	<ul style="list-style-type: none"> • SUNOSI 37.5 mg (n=56) • SUNOSI 75 mg (n=58) • SUNOSI 150 mg (n=116) • SUNOSI 300 mg (n=115; 2 times the maximum recommended daily dose) • Placebo (n=114)
Entry Criteria	<ul style="list-style-type: none"> • ESS score ≥ 10 • Mean sleep latency <30 minutes as documented by the mean of the first 4 trials of the MWT
Co-primary Endpoints	Change from baseline to week 12 in: <ul style="list-style-type: none"> • Mean sleep latency on the MWT • ESS scores
Key Secondary Endpoint	Percentage of patients who reported improvement on the PGIC at week 12

ESS data in OSA >

MWT data in OSA >

PGIC data in OSA >

TONES 2 study design: EDS in narcolepsy

TONES 2: EXCESSIVE DAYTIME SLEEPINESS (EDS) IN NARCOLEPSY ^{2,5}	
Study Design	12-week, randomized, multicenter, double-blind, placebo-controlled, parallel-group study in adult patients with narcolepsy (N=231)
Study Arms	<ul style="list-style-type: none"> • SUNOSI 75 mg (n=59) • SUNOSI 150 mg (n=55) • SUNOSI 300 mg (n=59; 2 times the maximum recommended daily dose) • Placebo (n=58)
Entry Criteria	<ul style="list-style-type: none"> • ESS score ≥ 10 • Mean sleep latency < 25 minutes as documented by the mean of the first 4 trials of the MWT
Co-primary Endpoints	Change from baseline to week 12 in: <ul style="list-style-type: none"> • Mean sleep latency on the MWT • ESS scores
Key Secondary Endpoint	Percentage of patients who reported improvement on the PGIC at week 12

ESS data in narcolepsy >

MWT data in narcolepsy >

PGIC data in narcolepsy >

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