

**MEDICATION GUIDE**  
**SUNOSI® (suh-NOH-see)**  
**(solriamfetol)**  
**tablets, for oral use, CIV**

**What is SUNOSI?**

SUNOSI is a prescription medicine used to improve wakefulness in adults with excessive daytime sleepiness that is associated with narcolepsy or obstructive sleep apnea (OSA).

- It is not known if SUNOSI is safe and effective in children.
- SUNOSI is not for use to treat the underlying cause of airway obstruction in people with OSA. SUNOSI does not take the place of using your continuous positive airway pressure (CPAP) machine or other devices that your healthcare provider has prescribed for the treatment of OSA. It is important that you continue to use these treatments as prescribed by your healthcare provider.

**SUNOSI is a federally controlled substance (CIV) because it contains solriamfetol that can be a target for people who abuse prescription medicines or street drugs.** Keep SUNOSI in a safe place to protect it from theft. Never give your SUNOSI to anyone else, because it may cause death or harm them. Selling or giving away SUNOSI may harm others and is against the law. Tell your healthcare provider if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.

**Do not take SUNOSI** if you are taking or have stopped taking within the past 14 days a medicine used to treat depression called a monoamine oxidase inhibitor (MAOI).

**Before taking SUNOSI, tell your healthcare provider about all your medical conditions, including if you:**

- have heart problems or have had a heart attack
- have had a stroke
- have high blood pressure
- have kidney problems or diabetes
- have high cholesterol in your blood
- have a history of mental health problems, including psychosis and bipolar disorders
- have a history of drug or alcohol abuse or addiction
- are pregnant or planning to become pregnant. It is not known if SUNOSI will harm your unborn baby.
  - **Pregnancy Registry:** There is a pregnancy registry for women who take SUNOSI during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry. For more information or to participate in the registry, call 1-877-283-6220 or go to [www.SunosiPregnancyRegistry.com](http://www.SunosiPregnancyRegistry.com)
- are breastfeeding or plan to breastfeed. It is not known if SUNOSI passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take SUNOSI.

**Tell your healthcare provider about all the medicines you take**, including prescription or over-the-counter medicines, vitamins, or herbal supplements.

SUNOSI and some other medicines may affect each other causing possible serious side effects. SUNOSI may affect the way other medicines work and other medicines may affect the way SUNOSI works.

**Especially tell your healthcare provider** if you take a medicine used to treat depression called a monoamine oxidase inhibitor (MAOI).

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

**How should I take SUNOSI?**

- Take SUNOSI exactly as your healthcare provider tells you to. Do not change your dose of SUNOSI without talking to your healthcare provider.
- Your healthcare provider may need to change the dose of SUNOSI until it is the right dose for you.

- Take SUNOSI by mouth 1 time each day when you first wake up. Avoid taking SUNOSI within 9 hours of your planned bedtime. If you take SUNOSI too close to your bedtime, you may find it harder to go to sleep.
- SUNOSI can be taken with or without food.
- Depending on your prescribed dose, your healthcare provider may tell you to swallow your SUNOSI tablet whole or split the SUNOSI tablet in half at the score line in the middle of the tablet. Ask your healthcare provider if you have questions about how to split the SUNOSI tablet in half the right way.
- If you take too much SUNOSI, call your healthcare provider or go to the nearest hospital emergency room right away.

#### **What are the possible side effects of SUNOSI?**

##### **SUNOSI may cause serious side effects, including:**

- **Increased blood pressure and heart rate.** SUNOSI can cause blood pressure and heart rate increases that can increase the risk of heart attack, stroke, heart failure and death. Your healthcare provider should check your blood pressure before you start and during treatment with SUNOSI. Your healthcare provider may decrease your dose or tell you to stop taking SUNOSI if you develop high blood pressure that does not go away during treatment with SUNOSI.
- **Mental (psychiatric) symptoms including anxiety, problems sleeping (insomnia), irritability and agitation.** Tell your healthcare provider if you develop anxiety, problems sleeping, irritability, agitation. Your healthcare provider may change your dose or tell you to stop taking SUNOSI if you develop side effects during treatment with SUNOSI.

The most common side effects of SUNOSI include:

- headache
- decreased appetite
- problems sleeping
- nausea
- anxiety

These are not all the possible side effects of SUNOSI.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### **How should I store SUNOSI?**

- Store SUNOSI at room temperature between 68°F to 77°F (20°C to 25°C).
- Store SUNOSI in a safe place, like a locked cabinet.
- Dispose of remaining, unused, or expired SUNOSI by a medication take-back program at authorized collection sites such as retail pharmacies, hospital or clinic pharmacies, and law enforcement locations. If no take-back program or authorized collector is available, mix SUNOSI with an undesirable, nontoxic substance such as dirt, cat litter, or used coffee grounds to make it less appealing to children and pets. Place the mixture in a container such as a sealed plastic bag and throw away SUNOSI in the household trash.

**Keep SUNOSI and all medicines out of the reach of children.**

#### **General information about the safe and effective use of SUNOSI.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use SUNOSI for a condition for which it was not prescribed. Do not give SUNOSI to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about SUNOSI that is written for health professionals.

#### **What are the ingredients in SUNOSI?**

**Active Ingredient:** solriamfetol

**Inactive Ingredients:** hydroxypropyl cellulose and magnesium stearate. In addition, the film coating contains: iron oxide yellow, polyethylene glycol, polyvinyl alcohol, titanium dioxide, and talc.

Distributed by: Axsome Therapeutics, Inc. New York, NY 10007

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For more information, go to [www.SUNOSI.com](http://www.SUNOSI.com) or call 1-800-484-1672.