

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **SUNOSI**<sup>®</sup>

#### **solriamfetol tablets**

Read this carefully before you start taking **SUNOSI** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **SUNOSI**.

#### **What is SUNOSI used for?**

SUNOSI helps you feel less sleepy during the day. It is used for adults with:

- Narcolepsy - a condition that causes you to suddenly and unexpectedly feel very sleepy at any time
- Obstructive Sleep Apnea (OSA) - condition where your breathing stops for brief periods of time when you sleep. SUNOSI does not treat the underlying causes of airway obstruction in people with OSA. It is important that you continue to use your continuous positive airway pressure (CPAP) machine or other devices that your doctor has prescribed for the treatment of your OSA.

#### **How does SUNOSI work?**

It is thought that SUNOSI works by increasing the amount of the natural substances dopamine and norepinephrine in your brain.

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

Medicinal ingredients: solriamfetol (as solriamfetol hydrochloride)

Non-medicinal ingredients: hydroxypropyl cellulose and magnesium stearate. In addition, the film coating contains: iron oxide yellow, polyethylene glycol (Macrogol), polyvinyl alcohol, talc and titanium dioxide.

#### **SUNOSI comes in the following dosage forms:**

Film-coated tablet: 75 mg: a yellow to dark yellow/orange oblong tablet with “75” on one side and a **score line** on the opposite side. The 75 mg tablet can be broken into half (½) using the score line on the tablet.

Film-coated tablet: 150 mg: a yellow oblong tablet with “150” on one side. The 150 mg tablet cannot be broken in half (½).

#### **Do not use SUNOSI if:**

- you are allergic to solriamfetol or to any of the other ingredients in SUNOSI (listed in **What are the ingredients in SUNOSI?**)
- you are taking a type of medicine called a ‘monoamine oxidase inhibitor’ (MAOI) for depression or for Parkinson’s Disease, or you have taken a MAOI within the last 14 days.
- you have had a heart attack in the past 1 year
- you have or have had heart problems, such as:
  - chest pain (angina)
  - high blood pressure that is not under control

- irregular heart beat (arrhythmias)
- other serious heart conditions
- you have or have had kidney problems or end stage kidney failure

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take SUNOSI. Talk about any health conditions or problems you may have, including if you:**

- have heart problems or have had a heart attack
- have had a stroke, bleeding in the brain or problems with blood flow to the brain
- have high blood pressure
- take medicines that can increase your blood pressure or heart rate
- have kidney problems
- have a history of mental health problems, including psychosis and bipolar disorders. Your doctor should monitor you if you have any of these conditions.
- have a history of drug or alcohol abuse or addiction
- have an eye condition called angle closure glaucoma or have increased pressure in your eye(s)

**Other warnings you should know about:**

**Increased blood pressure and heart rate:** SUNOSI can cause an increase in your blood pressure and heart rate. This increases the risk of heart attack, stroke, heart failure and death. Your doctor should check your blood pressure before you start SUNOSI and during treatment. Your doctor may decrease your dose or tell you to stop taking SUNOSI if you develop high blood pressure.

**Changes in your mental state (psychiatric disorders):** Tell your doctor if you develop any of the side effects listed below at any time during treatment with SUNOSI. Your doctor may change your dose or tell you to stop taking SUNOSI.

- feeling anxious
- trouble sleeping (insomnia)
- feeling irritated
- feeling agitated
- have panic attacks

**Pregnancy and Contraception:** You should not get pregnant while taking SUNOSI. If you are of childbearing age you should use an effective method of birth control during treatment with SUNOSI. Your doctor may recommend that you join the Sunosi Pregnancy Registry. This registry is designed to monitor you if you were exposed to SUNOSI during pregnancy. You can also join on your own by:

- calling 1-877-283-6220
- contacting [www.SunosiPregnancyRegistry.com](http://www.SunosiPregnancyRegistry.com)

**Breastfeeding:** It is not known if SUNOSI passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take SUNOSI.

**Driving and using machinery:** SUNOSI can make you feel dizzy or affect your attention. Until you know how SUNOSI affects you, you should avoid driving, using machinery or doing tasks that require special attention, especially when:

- you first start treatment with SUNOSI
- your dose is changed

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with SUNOSI:**

- A medicine called a 'monoamine oxidase inhibitor' (MAOI) for depression or for Parkinson's Disease, or if you have taken a MAOI within the last 14 days
- Medicines that can increase your blood pressure or heart rate. This can include other medicines used to treat sleepiness in narcolepsy or OSA such as amphetamines, methylphenidate and modafinil.
- Medicines called 'dopaminergic agents.' These medicines can be used to treat Parkinson's Disease, depression, restless leg syndrome and Attention Deficit Hyperactivity Disorder (ADHD).

**How to take SUNOSI:**

- Take SUNOSI exactly as your doctor tells you.
- Take it in the morning when you wake up.

Avoid taking your dose within 9 hours of your planned bedtime. If you take SUNOSI too close to your bedtime or too late in the day (less than 9 hours before you plan on going to bed), you may find it harder to go to sleep.

**Usual dose:** Your doctor will tell you how much to take. Your dose will depend on your age, your health and how you respond to SUNOSI. Your doctor may change your dose to find the right dose for you.

**If your doctor tells you to take 37.5 mg, break the 75 mg in half (½) using the score line on the tablet**

- For narcolepsy: the usual starting dose is 75 mg once a day in the morning when you wake up.
- For Obstructive Sleep Apnea (OSA): the usual starting dose is 37.5 mg once a day in the morning when you wake up.

**Overdose:**

If you think you, or a person you are caring for, have taken too much SUNOSI, contact a healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Symptoms of an overdose may include:

- uncontrolled movements
- feeling restless and unable to keep still

**Missed Dose:**

If you forget to take your dose at the usual time and it is:

- **Less than 9 hours** before your planned bedtime: **do not take this dose.** Take it the next day in the morning.
- **More than 9 hours** before your planned bedtime: you can take your dose as soon as you remember.

**What are possible side effects from using SUNOSI?**

These are not all the possible side effects you may have when taking SUNOSI. If you experience any side effects not listed here, tell your healthcare professional.

The most common side effects include:

- headache
- nausea
- vomiting
- diarrhea
- stomach pain
- constipation
- excessive sweating
- cough
- clenching or grinding your teeth
- dry mouth
- loss of appetite
- feeling anxious
- trouble sleeping (insomnia)
- fast or irregular heartbeat (palpitations)
- chest pain
- weight loss
- fever
- a cold
- sinus infection
- stiff joints and muscle aches and pain
- back pain
- increased frequency of urination during the day
- memory problems
- high blood pressure
- feeling dizzy

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<b>COMMON</b>			
<b>Heart problems:</b> increased blood pressure and heart rate		√	
<b>Psychiatric disorders:</b> feeling anxious, trouble sleeping, feeling irritable, feeling agitated, panic attacks		√	
<b>Hypersensitivity</b> (allergic reaction): fever, skin rash, hives, itching, swelling, shortness of breath, wheezing, runny nose, itchy, watery eyes			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

### **Storage:**

Store SUNOSI at room temperature between 15°C to 30°C.

Keep out of reach and sight of children.

### **If you want more information about SUNOSI:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); or the manufacturer's website at [www.axsome.com/axs-portfolio/products](http://www.axsome.com/axs-portfolio/products), calling 1-888-858-9666 or emailing [medinfo.ca@axsome.com](mailto:medinfo.ca@axsome.com).

This leaflet was prepared by Axsome Malta Ltd.

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