

Package leaflet: Information for the patient

Sunosi 75 mg film-coated tablets
Sunosi 150 mg film-coated tablets
solriamfetol

▼ **This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.**

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Sunosi is and what it is used for
2. What you need to know before you take Sunosi
3. How to take Sunosi
4. Possible side effects
5. How to store Sunosi
6. Contents of the pack and other information

1. What Sunosi is and what it is used for

Sunosi contains the active substance solriamfetol. Solriamfetol, increases the amount of the natural substances dopamine and norepinephrine in your brain. Sunosi helps you to stay awake and to feel less sleepy.

It is used

- in adults with narcolepsy, a condition that causes you to suddenly and unexpectedly feel very sleepy at any time. Some patients with narcolepsy also have symptoms of cataplexy (when muscles become weak in response to emotions such as anger, fear, laughter or surprise, sometimes leading to collapse).
- to improve wakefulness and reduce excessive daytime sleepiness (EDS) in adult patients with obstructive sleep apnoea (OSA) whose EDS has not been satisfactorily treated by primary OSA therapy, such as continuous positive airway pressure (CPAP).

2. What you need to know before you take Sunosi

Do not take Sunosi if you:

- are allergic to solriamfetol or any of the other ingredients of this medicine (listed in section 6)
- had a heart attack in the past 1 year
- have serious heart problems, such as chest pain of recent onset, or chest pain that is lasting longer or is more severe than usual, high blood pressure not properly controlled with medicines, serious irregular heart beat or other serious heart problems

- are taking a type of medicine called a ‘monoamine oxidase inhibitor’ (MAOI) for depression or Parkinson’s disease, or have taken an MAOI in the last 14 days.

Warnings and precautions

Talk to your doctor or pharmacist before taking Sunosi if you have or have had:

- mental health problems, including psychosis (altered sense of what is real) and extreme changes in mood (bipolar disorder)
- heart problems, heart attack or stroke
- high blood pressure
- alcoholism or any drug abuse or dependence
- an eye condition called angle closure glaucoma.

Tell your doctor or pharmacist if any of the above applies to you before starting treatment. This is because Sunosi may make some of these problems worse. Your doctor will want to monitor how the medicine affects you.

Sunosi does not replace your OSA primary treatment such as CPAP. You should continue to use such treatment as well as Sunosi.

Children and adolescents

Sunosi is not recommended in children or adolescents under 18 years of age. The safety and efficacy are not yet known in this age group.

Other medicines and Sunosi

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Sunosi if:

- you are taking a medicine called a ‘monoamine oxidase inhibitor’ (MAOI) for depression or Parkinson’s disease, or have taken an MAOI in the last 14 days because taking an MAOI with Sunosi may increase your blood pressure.

Check with your doctor or pharmacist if you are taking medicines that can increase your blood pressure or heart rate, or if you are taking dopaminergic agents (e.g. pramipexole, levodopa, methylphenidate) which are used to treat Parkinson’s disease, depression, restless leg syndrome and ADHD.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Sunosi should not be used during pregnancy or in women of childbearing potential not using effective contraception.

You should not use Sunosi during breast-feeding. You and your doctor must decide whether to avoid breast-feeding or to stop or avoid Sunosi therapy, taking into account the benefit of breast-feeding for you and your child and the benefit of therapy for you.

Driving and using machines

You may feel dizzy or your ability to concentrate may be impaired, take special care when driving or using machines.

Talk to your doctor or pharmacist if you are not sure how your underlying condition or this medicine affects you with activities that require attention, such as driving and handling machinery:

- at the beginning of treatment
- if your dose is changed

3. How to take Sunosi

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much Sunosi to take

Your doctor will advise you on the dose of Sunosi to take.

- For narcolepsy, treatment is normally started with a dose of 75 mg once per day, in the morning when you wake up. Some patients may need a 150-mg starting dose. Your doctor will advise you if this applies to you. Your doctor may prescribe you a lower dose of 37.5 mg. You can get this dose by taking half of one 75 mg tablet. The tablet should be broken using the score line.
- For OSA, treatment is normally started with a dose of 37.5 mg once per day, in the morning when you wake up. You can get this dose by taking half of one 75 mg tablet. The tablet should be broken using the score line.
- After at least 3 days' treatment, your doctor may increase your daily dose to the most appropriate dose.

The recommended maximum dose of Sunosi is 150 mg daily.

Elderly (aged more than 65 years)

Take the usual daily dose unless you have kidney problems (see below "Patients with kidney problems").

Patients with kidney problems

If you have kidney problems your doctor may need to adjust the dose.

Taking Sunosi

- Sunosi is for oral use
- Take Sunosi by mouth in the morning when you wake up.
- You can take Sunosi with food or between meals.

How long to take Sunosi

You should continue to take Sunosi for as long as you are told to by your doctor.

If you take more Sunosi than you should

The following symptoms were observed when patient received Sunosi 900mg (6 times the maximum daily dose): uncontrollable movements (tardive dyskinesia) and feeling restless and unable to keep still (akathisia). These symptoms resolved when Sunosi was stopped.

Contact your doctor or nearest emergency department immediately for advice. Take this leaflet and any remaining tablets with you.

If you forget to take Sunosi

If you forget to take your medicine at the usual time, you can still take it if it is more than 9 hours before bedtime. Do not take a double dose to make up for a forgotten dose.

If you stop taking Sunosi

Discuss with your doctor before you stop taking Sunosi.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common side effects (may affect more than 1 in 10 people)

- Headache

Common side effects (may affect up to 1 in 10 people)

- Anxiety, difficulty sleeping, irritability, dizziness, feeling jittery, excessive sweating
- Fast or irregular heart beats, also called palpitations, chest discomfort
- High blood pressure
- Feeling sick, diarrhoea, stomach pain, constipation, vomiting
- Cough, clenching or grinding your teeth, dry mouth
- Loss of appetite

Uncommon side effects (may affect up to 1 in 100 people)

- Feeling agitated, restlessness, inability to concentrate, shaking (tremors)
- Increase in heart rate much higher than normal
- Shortness of breath
- Chest pain
- Thirst
- Weight loss.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system](#) listed in [Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Sunosi

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the bottle / blister after "EXP". The expiry date refers to the last day of that month.

Blisters: This medicine does not require any special storage conditions.

Bottles: Once opened, use within 4 months. Keep the container tightly closed in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Sunosi contains

The active substance is solriamfetol.

Sunosi 75 mg film-coated tablets

Each tablet contains solriamfetol hydrochloride, equivalent to 75 mg of solriamfetol.

Sunosi 150 mg film-coated tablets

Each tablet contains solriamfetol hydrochloride, equivalent to 150 mg of solriamfetol.

The other ingredients are:

Tablet cores: Hydroxypropyl cellulose, magnesium stearate

Film coating: polyvinyl alcohol, macrogol, talc, titanium dioxide (E171), iron oxide yellow (E172).

What Sunosi looks like and contents of the pack

Film-coated tablet

Sunosi 75 mg film-coated tablets

Yellow to dark yellow/orange oblong tablet with “75” debossed on one side and a score line on the opposite side. The tablet can be divided into equal doses.

Sunosi 150 mg film-coated tablets

Yellow oblong tablet with “150” debossed on one side.

Sunosi is available in blister packs of 7, 28 and 56 film-coated tablets and in bottles of 30 and 100 film-coated tablets.

Not all pack sizes may be marketed.

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>.