Patient leaflet in accordance with the Pharmacists' Regulations (Medicinal Products) - 1986

This medicine is dispensed with a doctor's prescription only

SUNOSI® 75 mg

SUNOSI® 150 mg

Film-coated tablets

Active ingredient: The active substance is solriamfetol.

Sunosi® 75 mg

Each tablet contains 89.25 mg solriamfetol hydrochloride, equivalent to 75 mg of solriamfetol.

Sunosi® 150 mg

Each tablet contains 178.50 mg solriamfetol hydrochloride, equivalent to 150 mg of solriamfetol.

For the list of excipients in the medicinal product, please see section 6: "Additional information".

Read the entire leaflet carefully before you start using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, contact the physician or the pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

- Sunosi is indicated to improve wakefulness and reduce excessive daytime sleepiness in adult patients with narcolepsy (with or without cataplexy).
- Sunosi is indicated 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).

Therapeutic group: psychoanaleptics (stimulating), centrally acting sympathomimetics.

2. Before using this medicine:

Do not use the medicine if you:

- Are hypersensitive (allergic) to the active ingredient solriamfetol or any of the other ingredients that this medicine contains.
- Had a heart attack in the past 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.

Special warnings regarding the use of this medicine:

Before taking Sunosi, tell your doctor 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. There is no data concerning the safety and efficacy in children and adolescence.

Drug interactions:

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist. In particular, if you take:

'Monoamine oxidase inhibitors' (MAOI) – 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.

Consult 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.

Use of the medicine and food:

You can take Sunosi with food or between meals.

Pregnancy, breastfeeding and fertility:

The information about the use of Sunosi in pregnant women is limited.
If you are pregnant or breastfeeding, think you may be pregnant or are planning to get pregnant, 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.
Solriamfetol has been identified in breastfed newborns/infants of treated women. There are no data to determine the effects of solriamfetol on breastfed newborn/infants or its effects on milk production. A decision must be made whether to discontinue breastfeeding or to discontinue/abstain from SUNOSI therapy taking into account the benefits of breastfeeding for the child and the benefits of the therapy for the women.
Infants exposed to SUNOSI should be monitored for signs of agitation, insomnia, and reduced weight gain.

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 or if your dose is changed.

3. How to use the medicine?

Always use the medicinal product according to the doctor's instructions.
Check with your doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicinal product.
The dosage and treatment regimen will be determined only by the doctor.
The commonly recommended dose is:

- 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.
Do not exceed the recommended dose.

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.

Route of administration

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

Crushing/dividing/chewing

75 mg tablet – can be divided using the score line to receive a 37.5 mg dosage according to the doctor's instructions. Do not crush/chew.
150 mg tablet – the tablets cannot be divided. Do not crush/chew.

If you have accidentally taken a higher dosage

If you have taken more Sunosi than you should, consult your doctor.
The following symptoms were observed when patients 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.
If you have taken a higher dose or if a child has taken the medicine, contact your doctor or nearest emergency department immediately for advice and bring the drug product package with you.

If you forget to take the medicine

If you forget to take this 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.
You should continue the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

If you stop taking the medicine

Discuss with your doctor before you stop taking Sunosi.
Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take a medicine. Wear glasses if you need them.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Side effects:

As with any medicine, Sunosi can cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Very common side effects – effects that appear in more than one user out of ten

- Headache

Common side effects – effects that appear in 1-10 users out of 100

- 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 – effects that appear in 1-10 users out of 1,000

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

Skin rash, hives and itching have also been reported.

If a side effect appears, if any side effect gets worse or if you suffer from a side effect not mentioned in the leaflet, you should consult the doctor.

Reporting of side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" that appears on the homepage of the Ministry of Health's website (www.health.gov.il) which links to an online form for reporting side effects, or by the following link: https://sideeffects.health.gov.il/ and by emailing the registration holder's Patient Safety Unit at: drugsafety@neopharmgroup.com.

5. How to store the medicine?

Blisters: store below 25°C.
Bottles: store below 25°C. Keep the container tightly closed in order to protect from moisture. Once opened, use within 120 days, store below 25°C.
Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants to avoid poisoning. Do not induce vomiting without specific instruction from the doctor.
Do not use the medicine after the expiration date (exp. date) appearing on the packaging. The expiration date refers to the last day of that month.
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. Additional information

In addition to the active ingredient(s), the medicine also contains:
Hydroxypropyl cellulose (HPC), Magnesium stearate (MgSt), Polyvinyl alcohol, Polyethylene glycol (Macrogol), Titanium dioxide, Talc, Yellow iron oxide.

What does the medicine look like and what are the contents of the package:

Sunosi® 75 mg
Yellow to dark yellow/orange oblong tablet with "75" debossed on one side and a score line on the opposite side.

Sunosi® 150 mg
Yellow oblong tablet with "150" debossed on one side.
Sunosi is available in blister packs containing 7, 28 or 56 film-coated tablets and in bottles of 30 or 100 film-coated tablets.
Not all pack sizes may be marketed.

Manufacturer:

CILATUS MANUFACTURING SERVICES LIMITED, Dublin 2, Co. Dublin, D02 EK84, Ireland.

Registration holder:

NEOPHARM Ltd., Hashiloach 6, P.O.B. 7063, Petach Tikva 4917001

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Sunosi® 75 mg: 172-80-37284-99

Sunosi® 150 mg: 172-81-37285-99

This leaflet was checked and approved by the Ministry of Health in November 2023.