PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Stilnox 10 mg Tablets

Active ingredient and its quantity:
Each film-coated tablet contains: Zolpidem Tartrate 10 mg

Inactive and allergenic ingredients in the preparation – see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or 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.

WARNING: Zolpidem may be associated with unusual and potentially dangerous behaviors whilst apparently asleep. These behaviors include sleepwalking, driving motor vehicles and other bizarre behaviors. Certain medicines may interact with zolpidem and special caution is required during treatment with other medicines that may also act on the brain; before taking zolpidem, read the section "Drug interactions" below or consult the doctor or pharmacist. Do not drink alcohol when taking zolpidem. Do not take zolpidem for more than 4 weeks. If the sleep problems continue, consult the doctor.

1. WHAT IS THE MEDICINE INTENDED FOR?

Stilnox is indicated for the short-term treatment of occasional or transient insomnia in adults in situations where the insomnia is debilitating or is causing severe distress for the patient.
Therapeutic group: Hypnotic and sedative substances.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient (zolpidem) or to any of the additional ingredients contained in the medicine (see section 6). Always check the ingredients to be sure that you can use this medicine.
- You have been drinking alcohol or you believe that you may have alcohol in your bloodstream.
- You suffer from sleep apnea (a disturbance in which you temporarily stop breathing during sleep).
- You suffer from myasthenia gravis (a disturbance in which the muscles weaken and tire easily).
- You suffer from severe liver problems.
- You suffer from acute and/or severe lung problems.

- You have experienced in the past complex sleep behaviors after taking this medicine, including sleepwalking, sleep driving and/or engagement in other activities when you are not fully awake.

Special warnings regarding use of the medicine

- Tell the doctors, dentists and pharmacists treating you that you are taking Stilnox.
- If you are due to start treatment with a new medicine, tell the doctor and pharmacist that you are taking Stilnox.
- If you plan to undergo surgery that requires general anesthesia, tell the doctor or dentist that you are taking this medicine.

Before treatment with the medicine, tell the doctor if:

- you experience breathing problems or if you often snore while sleeping.
- you have ever been addicted to alcohol, a drug or medicine, or if you have ever suffered from mental illness. If so, you may be at risk of developing a permanent pattern or habit of taking Stilnox.
- you are suffering or have suffered from other medical disturbances, particularly those listed below: heart, liver, kidney, or lung problems, epilepsy, depression, mental illness, e.g., schizophrenia.
- you plan to undergo surgery.
- you suffer from allergies to one of the ingredients listed at the end of this leaflet.
- you are taking medicines to treat another disorder.

Talk to the doctor or pharmacist if you have ever suffered from a mental disorder, or suffered from alcohol or drug abuse or dependence.

During the course of treatment, you may be at risk of developing certain side effects. It is important that you understand these risks and know how to monitor them. See additional information in section 4 “Side effects”.

Additional warnings:

- If you are over the age of 65 and you are unwell or are taking other medicines, you may be more sensitive to some of the side effects of Stilnox. Some patients may be particularly susceptible to the sedative effects of the medicine, which may increase the likelihood of falls.
- Stilnox can cause drowsiness and a decreased level of consciousness. Store Stilnox in a safe place to protect it from theft, since it may be used illicitly for criminal activities (which may be dangerous), especially in combination with alcohol, when given without knowledge of a victim. Never give Stilnox to other people as it may harm them.
- In most cases, sleep medicines should be used for short periods of time only. If the sleep problems persist, consult with the doctor.
- Certain medicines can cause dependence, especially when they are used regularly for more than a few weeks. People who have been dependent on alcohol or medicines in the past may be at increased risk of addiction to sleep medicines. If you have been addicted to alcohol or medicines in the past, it is important that you report it to the doctor before starting use of Stilnox.
- Withdrawal symptoms can sometimes occur when treatment with a medicine is abruptly discontinued after prolonged use. Withdrawal symptoms may include abdominal and muscle cramps, vomiting and sweating. In some cases, insomnia may worsen for a short period of time, which may be

accompanied by additional reactions, including mood changes, anxiety and restlessness; speak with the doctor if these effects occur. Patients who took part in trials did not experience any problems when Stilnox was discontinued. Nonetheless, report to the doctor if you experience problems after stopping treatment with Stilnox.

Children and adolescents:

Do not give Stilnox to a child or adolescent under the age of 18; there is no experience with its use in children and adolescents under the age of 18.

Drug interactions:

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist**. Certain medicines may disrupt the effect of Stilnox and affect how it works.**

Medicines that may <u>increase</u> the effect of Stilnox include:

- alcohol
- medicines to treat depression, anxiety and mental illness
- medicines used for calming or to facilitate sleep
- medicines to treat epilepsy
- pain relievers
- muscle relaxants
- antihistamines
- ciprofloxacin, a medicine used to treat infections
- ketoconazole, a medicine to treat fungal infections
- opioids

These medicines may increase drowsiness. This may affect ability to drive a car or to operate dangerous machinery. You may need to use different amounts of the medicine, or to take different medicines. The doctor will advise you.

Medicines that may <u>reduce</u> the effect of Stilnox include:

- St. John's wort (also known as Hypericum), a herbal medicine used to treat depression
- rifampicin, a medicine used to treat infection

Check with the doctor or pharmacist if you are not sure about the medicines, vitamins or supplements you are taking and about their possible effect on Stilnox.

Use of the medicine and alcohol consumption:

Do not drink alcohol before or after taking this medicine. This may increase the risk of side effects or the effects of alcohol may worsen while taking Stilnox .
Tell the doctor if you drink alcohol.

Pregnancy and breastfeeding:

Consult the doctor if you are pregnant, suspect that you are pregnant, or intend to become pregnant.
Like most medicines of this kind, Stilnox is not recommended for use during pregnancy. The doctor will discuss the risks and benefits of taking it if you are pregnant.

If you become pregnant or suspect that you are pregnant while taking this medicine, stop taking it and report to the doctor or pharmacist immediately.
Talk to the doctor if you are breastfeeding or intend to breastfeed.
Stilnox can pass into breast milk. The doctor will discuss the risks and benefits of using it if you are breastfeeding or intend to breastfeed.

Driving and operating machinery:

Since Stilnox may cause drowsiness, do not operate dangerous machinery or drive motor vehicles for 8 hours after taking it. You should also be careful when you wake up the next morning.
Before driving or operating machinery, make sure that you know how you will react to Stilnox. This is very important if you are taking other medicines which also cause drowsiness.

Important information about some of the ingredients of the medicine:

The medicine contains **lactose**. Consult your doctor before starting to use this medicine if you have an intolerance to certain sugars.

3. HOW SHOULD THE MEDICINE BE USED?

Always use the preparation according to the doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
The dosage and treatment regimen will be determined by the doctor only.
The usual dosage is generally:
If needed, take only one Stilnox tablet at night, immediately before bedtime.
The usual starting dosage is generally: For women – 5 mg (half a tablet) once a day. For men – 5-10 mg once a day.
In the elderly and patients with liver function problems, the dosage is 5 mg (half a tablet) once a day. Do not use if you have been diagnosed with severe liver failure.
Do not exceed a dosage of 10 mg once a day, immediately before bedtime.
Make sure that you will be able to sleep for at least 7-8 hours after taking the medicine.
Do not exceed the dose recommended by the attending doctor.
Do not take Stilnox if you drank alcohol that evening or before bedtime.
Do not take Stilnox with or immediately after a meal. Stilnox can help you fall asleep faster if taken on an empty stomach.

Duration of treatment:

Stilnox is intended for short-term use only. Treatment with Stilnox must be as short as possible since the risk of dependence increases with more prolonged treatment.
The usual duration of treatment with the medicine is two days to four weeks. Refer to your doctor if your insomnia worsens or does not improve within 7-10 days. This may indicate that there is another medical condition that is causing your sleep problems.

In some patients, the higher levels of the medicine in the blood in the morning, after taking 10 mg before bedtime, increase the risk of impaired alertness, ability to drive and ability to concentrate.
The tablets are not intended for children and adolescents under 18 years of age.

Method of administration:

Swallow the tablet whole, unless the doctor has told you take 5 mg (half a tablet).
The tablet can be halved.
There is no information regarding crushing or chewing.

If you accidentally took a higher dosage or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine:

Take the medicine immediately before going to sleep only if you will be able to sleep for at least 7-8 hours. If you forgot to take the medicine before bedtime, do not take a dose at any other time as you may feel drowsy, dizzy and confused during the day.
Do not take a double dose to compensate for the forgotten dose. Take the next dose at the usual time and consult the doctor.
Adhere to the treatment regimen recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with Stilnox without consulting the doctor and even then, only gradually.

If you stop taking the medicine:

The following reactions may occur one or two days after you stop taking the medicine: sleep problems, nausea, flushing, dizziness, uncontrollable crying, vomiting, abdominal cramps, anxiety attack, nervousness and pain in the stomach area.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Stilnox may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
If you do not feel well while taking Stilnox, tell the doctor as soon as possible.

Stilnox may cause serious side effects, including:

<u>Allergic reactions</u>:

- Swelling of the face, lips, mouth or throat, which may cause difficulty swallowing or breathing
- Hives
- Fainting

Sleepwalking and associated behaviors:

Sleepwalking, driving motor vehicles and other unusual, and on some occasions dangerous, behaviors whilst apparently asleep. These behaviors also include preparing and eating food, making phone calls or having sexual intercourse. People who experienced these effects had no memory of the events.

Refer to a doctor immediately or proceed to the closest hospital emergency room if you notice any of these serious side effects.

Alcohol can increase the risk of sleepwalking and other related behaviors. These side effects can also occur without the presence of alcohol. Even though these side effects can occur at the usual recommended dosages, the risk of these behaviors occurring may be increased if you take more than the recommended dosage.

Some sleep medicines may cause a short-term memory loss. When this occurs, a person may not remember what has happened for several hours after taking the medicine. This is usually not a problem since most people fall asleep after taking this medicine.

Less serious side effects:

Head- and neurology-related:

- drowsiness
- dizziness
- headache
- fatigue
- anxiety
- nightmares
- poor attention and concentration
- memory impairment and loss
- unexpected changes in behavior - these include rage reactions, worsened insomnia, confusion, agitation, depression, hallucinations, delirium, and other forms of unwanted behavior

Gastrointestinal system-related:

- diarrhea, nausea and vomiting
- abdominal pain

Musculoskeletal system-related:

- muscle weakness
- back pain

Infection-related:

- infections of the nose, throat and respiratory tract

Although these side effects can occur at the usual recommended dosages, the risk of onset of these behaviors may be increased if you take a dosage higher than the recommended dosage.
Talk to the doctor if you experience one of these less serious side effects and it concerns you.

Tell the doctor or pharmacist if you notice another effect that may cause you to feel unwell. Additional side effects that are not listed here may occur in some people. If any question arises, refer to the doctor.

If a side effect occurs, if one of the side effects worsens, or persists for more than a few days, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il/

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be stored in a safe place, out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
Do not take the medicine if the package is damaged or shows signs of tampering.
Storage conditions: Store at a temperature below 25°C.
If you have no further need for this medicine or if it has expired, bring it to the pharmacy for safe disposal.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Lactose monohydrate, microcrystalline cellulose, hypromellose, sodium starch glycollate and magnesium stearate. The coating on the tablets consists of hypromellose, titanium dioxide and macrogol 400.

Each tablet contains 90.4 mg lactose monohydrate.

What the medicine looks like and the contents of the package: A white/cream-colored film-coated tablet. Available in packages of 7, 14 or 20 tablets. Not all package sizes may be marketed.

This leaflet does not contain all the information about the medicine. If you have any question or are not sure about anything, please refer to the doctor.

Registration Holder and Importer and address: Sanofi Israel, Ltd., Greenwork Park , P.O. box 47, Yakum.

Revised in September 2025 in accordance with the MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1045127587

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