PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
The medicine is dispensed with a doctor's prescription only

Stilnox 10 mg Tablets

SANOFI

Active ingredient and its quantity:
Each 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 this 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.
This medicine is not intended for children and adolescents under the age of 18.

1. WHAT IS THE MEDICINE INTENDED FOR?

For the treatment of insomnia.

Therapeutic group: Hypnotic and sedative substances.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You have ever experienced complex sleep behavior (such as driving a car, making and eating food, talking on the phone or having sex while not being fully awake) after taking Stilnox.
- You are sensitive (allergic) to the active ingredient (zolpidem) or to any of the additional ingredients contained in the medicine (see section 6).
- You have suffered in the past from an allergic reaction to zolpidem-containing medicines. Symptoms of severe allergic reaction to zolpidem may include: swelling of your face, lips and throat that may cause difficulty in breathing or swallowing.
- You are suffering from severe liver failure.
- You drank alcohol in the evening or before bedtime.
- You took another medicine intended to help you sleep.
- You will not be able to get a full night's sleep after taking the medicine (7-8 hours) before you need to be active again.

Special warnings regarding use of the medicine:

- **Do not take more Stilnox than prescribed.**
- Stilnox should be taken immediately before bedtime, not earlier.
- Do not use the medicine for more than four consecutive weeks! Prolonged use may cause dependency.
- If the effect of the medicine has declined following repeated use, do not increase the dosage.
  Similar to other hypnotic preparations, uncontrolled discontinuation of treatment may be rarely accompanied by withdrawal effects, e.g., muscle cramps, tremor, recurrence of insomnia, abdominal pains, vomiting, nausea, sweating, convulsions.
- **Stilnox may cause severe side effects, including:**
  Complex sleep behaviors, which have caused severe injury and death. After taking Stilnox, you may get out of bed when you are not fully awake and engage in activities that you are not aware that you are doing (complex sleep behaviors). The next morning, you may not remember that you did something during the night. These activities can occur with Stilnox, whether you do or do not drink alcohol or are taking other medicines that cause you to be sleepy.

Activities which have been reported include:

- driving a car ("sleep driving")
- making and eating food
- talking on the phone
- having sex
- sleepwalking

Stop taking Stilnox and refer to your doctor immediately if you realize that you performed one of the activities described above after taking Stilnox.

- Store Stilnox in a safe place to avoid incorrect use or abuse. Tell your doctor if you have abused or developed a dependency on alcohol, prescription medicines or drugs in the past.
- If an acute allergic reaction to the medicine develops, manifested by angioedema (edema of the tongue, glottis [the opening to the trachea], larynx [the voice box]), do not use this medicine again.
- In the elderly – use benzodiazepines and similar medicines with caution, since there is risk of sleepiness and/or muscle flaccidity that may lead to falls, frequently with serious consequences in this population.
- A reduced dosage (5 mg) is advisable in the elderly, in women and in patients with liver function problems, see section 3.
- Use of Stilnox together with other medicines possessing a tranquilizing effect (e.g., medicines from the benzodiazepine group, opioids, certain antidepressants, alcohol), increases the risk of central nervous system depression. If Stilnox is taken concomitantly with these medicines, the attending doctor must consider adjusting the dosage of the medicines. Do not take Stilnox together with medicines possessing a hypnotic sedative effect (including other zolpidem-containing medicines) before bedtime or at night, unless your doctor has instructed you to do so.
- The risk of psychomotor impairment the morning after taking Stilnox, including impaired driving ability, increases if the medicine is taken at bedtime, without the possibility of 7-8 hours of sleep, if a dosage higher than that recommended by the doctor is taken, if taken in combination with other central nervous system depressants or alcohol, or if taken in combination with other medicines that may increase the levels of zolpidem in the blood. In these cases, patients must exercise caution with regards to driving or engaging in other activities that require brain functioning and full alertness.
- Stilnox may cause drowsiness and decreased level of alertness which may cause falls, and, as a result, even lead to severe injuries. There have been reports of severe injuries such as hip fractures and intracranial hemorrhage.

Before treatment with the medicine, tell the doctor if:

- You have a history of depression, mental illnesses, or suicidal thoughts.
- You have a history of alcohol abuse or addiction.
- You are suffering from a kidney or liver disease.
- You are suffering from a lung disease or from breathing problems.
- You are pregnant, planning a pregnancy, breastfeeding or planning to breastfeed.

Children and adolescents:
The tablets are not recommended for treatment of children and adolescents under 18 years of age, since the effectiveness and safety of use of the medicine in these ages have not been proven.

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking:
Central nervous system depressants, e.g., medicines from the benzodiazepine group, opioids, tricyclic antidepressants and alcohol – see "Special warnings regarding use of the medicine" section.
Sertraline, fluoxetine, fluvoxamine – antidepressants.
Chlorpromazine, haloperidol – for treatment of mental illnesses.
St. John's wort (Hypericum).
Rifampin, ciprofloxacin – for treatment of infections.
Ketoconazole – for treatment of fungi.
Medicines may affect each other's activity and sometimes cause severe side effects.
Do not take Stilnox with other medicines that may make you sleepy unless you have been instructed to do so by your doctor.
Know the medicines you are taking. Keep a list of your medicines to show your doctor and pharmacist each time you receive a new medicine.

Use of the medicine and food
Do not take the medicine with a meal or immediately after a meal. The activity of the medicine is faster if it is taken on an empty stomach.

Use of the medicine and alcohol consumption
Do not drink wines or alcoholic beverages during the course of treatment with the medicine.

Pregnancy, breastfeeding and fertility
If you are pregnant or planning a pregnancy, breastfeeding or planning to breastfeed, consult a doctor before using the medicine.
If you are pregnant, planning a pregnancy, talk to your doctor about the risk to the unborn baby if you use Stilnox.
Use of Stilnox in the last trimester of pregnancy may cause breathing difficulties or excessive sleepiness in the newborn. Monitor for signs of sleepiness (more than usual), breathing problems or flaccidity in the newborn if Stilnox was taken at the end of the pregnancy.
If you are breastfeeding or planning to breastfeed, Stilnox passes into breast milk. Consult a doctor regarding the optimal way of feeding your baby while you are using Stilnox.

Driving and operating machinery
Use of the medicine may impair alertness and therefore requires caution when driving a car, operating dangerous machinery and when engaging in any activity which requires alertness.
You may feel dizzy, even the day after taking Stilnox.
The risk of a psychomotor impairment, including impaired ability to drive, increases if the medicine is taken at bedtime without the possibility of 7-8 hours of sleep, if a dosage higher than that recommended by the doctor is taken, if taken in combination with other central nervous system depressants or alcohol, or if taken in combination with other medicines that may increase zolpidem levels in the blood.
The medicine may affect your ability to concentrate on the following day, even if you feel fully alert.
Those who drive a car and those who operate machinery must know that as with other hypnotics (sleep medicines), there may be a potential risk of side effects, including drowsiness, prolonged response time, dizziness, sleepiness, blurred/double vision, reduced alertness and impaired driving the morning after taking the treatment. To reduce the risk, it is recommended to get a full night of sleep (7-8 hours).

Important information about some of the ingredients of the medicine
The medicine contains **lactose**. Consult your doctor before starting use of the medicine if you suffer from intolerance to certain sugars.

3. HOW SHOULD YOU USE THE MEDICINE?

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 the 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 initial 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 severe liver failure has been diagnosed.
Do not exceed a dosage of 10 mg, once a day, immediately before bedtime.
Make sure that you can sleep at least 7-8 hours after taking the medicine.

Do not exceed the dosage recommended by the attending doctor.

Do not take Stilnox if you drank alcohol on the same evening or before bedtime.
Do not take Stilnox with or immediately after a meal. Stilnox can help you fall asleep faster if you take it on an empty stomach.

Treatment duration

The usual duration of treatment with the medicine is two days to four weeks.
Contact 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 the sleep problems.
In some patients, the higher levels of the medicine in the blood in the morning, after taking 10 mg at bedtime, increase the risk of impaired alertness, driving ability and ability to concentrate.
The tablets are not intended for children and adolescents under 18 years of age.

Mode of administration

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

Take the medicine immediately before bedtime, and only if you can then 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 throughout 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 as 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:

One or two days after stopping the sleep medicine, the following reactions may occur: sleep problems, nausea, flushing, dizziness, uncontrollable crying, vomiting, abdominal cramps, an anxiety attack, nervousness and pain in the stomach area.

Do not take medicines in the dark! Check the label and dose each time 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 by the list of side effects. You may not suffer from any of them.
Severe side effects include:

- Getting out of bed when you are not fully awake and performing activities that you are not aware that you performed (see section 2 "Special warnings regarding use of the medicine").
- Unusual thoughts and behaviors. The symptoms include more social or aggressive behavior than usual, confusion, agitation, hallucinations, worsening of depression and suicidal thoughts or actions.
- Memory loss.
- Anxiety.
- Severe allergic reactions. The symptoms include swelling of the tongue or throat and breathing problems. Seek urgent medical attention if these symptoms occur after taking Stilnox.
- Falls which may lead to severe injuries.

Contact the doctor immediately if any side effects listed above or other side effects that concern you occur while using Stilnox.
Common side effects (affect more than 1/100 patients):
Dry mouth, weakness, unstable walk (ataxia), confusion, drowsiness, stupor or a sensation of being under the effect of a drug, euphoria, headache, insomnia, dizziness, vertigo, diarrhea, dyspepsia, hiccups, nausea, sinusitis, vision disturbances, urinary tract infections, joint pain, muscle pain, upper respiratory tract infection, lower respiratory tract infection.
Uncommon side effects (affect between 1/100 and 1/1000 patients):
Increased sweating, pallor, orthostatic hypotension, fainting, chest pains, edema, falls (which may cause serious injuries), exhaustion, fever, general unwell feeling, trauma, cerebrovascular disturbances, hypertension, tachycardia, agitation, anxiety, decreased brain function, feeling detached, concentration difficulties, speech impairment, emotional instability, hallucinations, hypoesthesia, illusions, leg muscle cramps, migraine, nervousness, sensation problem, sleeping (after taking the medicine during the day), dulled senses, tremor, anorexia, constipation, swallowing impairment, bloating (flatulence), inflammation in the digestive system, vomiting, infection, impaired liver function and increased level of enzymes, hyperglycemia, thirst, arthritis, irregular menstrual cycle, vaginal inflammation, bronchitis, cough, shortness of breath, nasal inflammation (rhinitis), itch, eye irritation, eye pain, eye inflammation, change in taste, tinnitus, bladder inflammation, urinary incontinence.
Rare side effects (affect less than 1/1000 patients):
Vision disturbances, altered saliva, flushing, glaucoma, decreased blood pressure, impotence, increased secretion of saliva, tenesmus, allergic reaction, aggravation of allergy, anaphylactic shock, facial edema, hot flushes, accelerated blood sedimentation, pain, restless leg syndrome, muscle stiffness, increased tolerance to the medicine, weight loss, angina pectoris, arrhythmia, arteritis, blood circulation problems, excessive heart beats, aggravated hypertension, heart attack, phlebitis, varicose veins, pulmonary embolism, pulmonary edema, ventricular tachycardia, gait disturbances, abnormal thoughts, aggressive reaction, apathy, increased appetite, decreased libido, delusions, dementia, speech disturbances, depersonalization, strange feeling, movement disorders, hypotonia, hysteria, intoxicated feeling, manic reaction, nerve pain, nerve inflammation, neuropathy (a peripheral nervous system disease), neurotic disturbance, panic attacks, partial paralysis, personality disorders, sleepwalking, suicide attempts, severe muscle cramping, yawning, intestinal inflammation, belching, esophagospasm, gastritis, hemorrhoids, intestinal obstruction, rectal hemorrhage, dental caries, anemia, hyperhemoglobinemia, leukopenia, enlarged lymph nodes, macrocytic anemia, purpura (patch -like rash), thrombosis, abscess, herpes, herpes zoster, middle or outer ear infection, increased bilirubin levels, increased liver enzyme levels, gout, hypercholesteremia or hyperlipidemia, kidney function disorders, periocular edema, joint disease, muscle weakness, pain radiating to the leg, tendinitis, breast tumors, breast pain, bronchospasm, respiratory depression, nose bleed, reduced blood oxygen, inflammation of the throat, pneumonia, acne, bullous rash, dermatitis, pustular rash, photosensitivity, urticaria, conjunctivitis, corneal ulceration, lacrimation disorders, smell identification disturbance, light flashes, severe renal failure, painful or frequent urination, nocturia, polyuria, renal inflammation, renal pain, urinary retention.
Side effects of **unknown frequency**:
Severe liver damage, with or without jaundice.
Side effects upon discontinuation of the medicine – see details in section 3.

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 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 kept 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.
Storage conditions: Store at a temperature below 25°C.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Lactose monohydrate, microcrystalline cellulose, hypromellose, sodium starch glycolate (type A), titanium dioxide suspension, magnesium stearate 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 20 tablets.
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 its address: sanofi-aventis Israel ltd., P.O.B. 8090, Netanya 4250499.
Revised in May 2021 according to MOHs guidelines.
Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1045127587