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

Zodorm 10

Tablets

The active ingredient and its quantity:
Each **Zodorm 10** tablet contains:
Zolpidem Tartrate 10 mg
Inactive and allergenic ingredients in the preparation – see in 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.
This medicine is not intended for children and adolescents below 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 unconscious behavior during sleep (e.g., driving a car, preparing and eating food, talking on the phone or having sex while not being fully awake) after taking **Zodorm 10**.
- You are sensitive (allergic) to the active ingredient (zolpidem) or to any of the other ingredients contained in the medicine (see section 6 "Further Information").
- You have suffered in the past from an allergic reaction to zolpidem-containing medicines. Symptoms of a severe allergic reaction to zolpidem can include: swelling of the face, lips and throat that may cause breathing and swallowing difficulties.
- You suffer from severe liver failure.
- You drank alcohol in the evening or before bedtime.
- You took another medicine intended to help you fall asleep.
- 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 **Zodorm 10** than the doctor has prescribed for you.
- Take **Zodorm 10** just before bedtime, not earlier.
- Do not use the medicine for more than four consecutive weeks! Prolonged use may cause dependence.
- If the effect of the medicine has declined following repeated use, do not increase the dosage.
- Similarly to other sleeping pills, stopping treatment in an uncontrolled manner may on rare occasions be accompanied by withdrawal effects, e.g., muscle cramps, tremor, recurrence of insomnia, abdominal pain, vomiting, nausea, sweating, convulsions.

Zodorm 10 may cause severe side effects, including:
- Unconscious behaviors during sleep, which has caused serious injury and death. After taking **Zodorm 10**, you may get out of bed when you are not fully awake and engage in activities without being aware that you are doing them (unconscious behaviors during sleep). The next morning, you may not remember that you did something at night. These activities can occur with **Zodorm 10** whether or not you drink alcohol or take other medicines that cause you to be sleepy. Activities that have been reported include:
  - Driving a car ("sleep driving")
  - Preparing and eating food
  - Talking on the phone
  - Having sex
  - Sleepwalking.

  Stop taking **Zodorm 10** and refer to your doctor immediately if you find out that you performed one of the activities described above after taking **Zodorm 10**.
- Keep **Zodorm 10** in a safe place in order to avoid incorrect use or abuse. Tell the doctor if you have abused or become dependent on alcohol, prescription medicines or drugs in the past.
- If you develop an acute allergic reaction to the medicine, manifested by angioedema (swelling of the tongue, swelling of the glottis [opening of the windpipe], swelling of the larynx [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 age group.
- A reduced dosage (5 mg) is advisable in the elderly, in women and in patients with liver function problems; see section 3.
- Use of **Zodorm 10** together with other medicines possessing a sedative effect (e.g., medicines from the benzodiazepine group, opioids, certain antidepressants, alcohol) increases the risk of central nervous system depression. If **Zodorm 10** is taken concomitantly with these medicines, the attending doctor must consider adjusting the dosage of the medicines. Do not take **Zodorm 10** together with medicines possessing a sedative-hypnotic 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 in the morning after taking **Zodorm 10**, including impaired driving ability, increases if the medicine is taken before bedtime without a possibility of sleeping for 7-8 hours, 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 be especially cautious regarding driving or any other activity that requires brain function and full alertness.
- **Zodorm 10** may cause fuzziness 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 illness or suicidal thoughts.
- You have a history of alcohol abuse or addiction.
- You suffer from a kidney or liver disease.
- You suffer from a lung disease or 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 this age group have not been proven.
Drug interactions
If you are taking, or if you have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially, if you are taking:
- Central nervous system depressants, such as:
  Medicines from the benzodiazepine group, opioids, tricyclic antidepressants and alcohol – see in section 2 "Special warnings regarding use of the medicine".
- 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 Zodorm 10 with other medicines that may make you sleepy unless you have been instructed to do so by your doctor.
Know the medicines you take. Keep a list of the medicines you take so that you can show it to your doctor and pharmacist each time you receive a new medicine.
Use of the medicine and food
Do not take the medicine with 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, planning a pregnancy, breastfeeding or planning to breastfeed, consult a doctor before using the medicine.
If you are pregnant or planning a pregnancy, talk to your doctor about the risk to the unborn baby if you use **Zodorm 10**.
Use of **Zodorm 10** 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 **Zodorm 10** was taken at the end of the pregnancy.
If you are breastfeeding or planning to breastfeed, **Zodorm 10** passes into breast milk. Consult a doctor regarding the optimal way of feeding your baby while you are using **Zodorm 10**.
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 that requires alertness.
You may feel dizzy, even the day after taking **Zodorm 10**.
The risk of psychomotor impairment, including impaired driving ability, increases if the medicine is taken before bedtime without a possibility of sleeping for 7-8 hours, 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.
The medicine may affect your ability to concentrate on the following day, even if you feel fully alert.
Patient who drive a vehicle and patient 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 medicine. To reduce the risk, it is recommended to get a full night's sleep (7-8 hours).
Important information about some of the ingredients of the medicine
The medicine contains **lactose**. Consult your doctor before starting to use 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 for the preparation.
The dosage and treatment regimen will be determined by the doctor only.
The usual dosage is generally: If needed, take only one **Zodorm 10** 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 per day, immediately before bedtime. Be sure that you will be able to sleep for at least 7-8 hours after taking the medicine.
Do not exceed the recommended dose.
Do not take **Zodorm 10** if you drank alcohol on the same evening or before bedtime.
Do not take **Zodorm 10** with or immediately after a meal. **Zodorm 10** 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.
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 the 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 impairment of alertness, driving ability and capacity 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 instructed you to take 5 mg (half a tablet of **Zodorm 10**).
If necessary, the tablet can be halved for immediate use.
There is no information regarding crushing or chewing the tablet.
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 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 as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with **Zodorm 10** without consulting the doctor and even then, only gradually.
If you stop taking the medicine:
In the first day or two after you stop taking the medicine, the following effects 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 the 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 **Zodorm 10** 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.
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 in 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 treatment if these symptoms occur after taking **Zodorm 10.**
- Falls which may lead to severe injuries.

Contact the doctor immediately if any of the side effects described above or any other side effects that concern you occur while using **Zodorm 10.**
Common side effects – effects that occur in 1-10 in 100 users
Dry mouth, weakness, unstable walk (ataxia), confusion, drowsiness, stupor or sensation of being under the influence of a drug, euphoria, headache, insomnia, dizziness, vertigo, diarrhea, indigestion, hiccups, nausea, sinusitis, vision disturbances, urinary tract infections, joint pain, muscle pain, upper respiratory tract infection, lower respiratory tract infection.
Uncommon side effects – effects that occur in 1-10 in 1,000 users
Increased sweating, pallor, decrease in blood pressure when standing up, fainting, chest pain, edema, falls (which may cause serious injuries), exhaustion, fever, general unwell feeling, trauma, cerebrovascular disturbances, hypertension, rapid pulse, agitation, anxiety, decreased brain function, feeling detached, concentration difficulties, speech impairment, emotional instability, hallucinations, hypoesthesia, illusions, leg muscle cramps, migraine, nervousness, sensory 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 enzyme levels, hyperglycemia, thirst, arthritis, irregular menstrual cycle, vaginal inflammation, bronchitis, cough, shortness of breath, nasal inflammation (rhinitis), itch, eye irritation, eye pain, eye inflammation, altered taste, tinnitus, bladder inflammation, urinary incontinence.
Rare side effects – effects that occur in 1-10 in 10,000 users
Vision disturbances, altered saliva, flushing, glaucoma, reduced blood pressure, impotence, increased secretion of saliva, tenesmus, allergic reaction, aggravation of allergy, anaphylactic shock, facial edema, hot flushes, accelerated blood sedimentation rate, pain, restless leg syndrome, muscle stiffness, increased tolerance to the medicine, weight loss, angina pectoris, arrhythmia, arthritis, blood circulation problems, excessive heart beats, aggravation of high blood pressure, heart attack, phlebitis, varicose veins, pulmonary embolism, pulmonary edema, ventricular tachycardia, impaired walking, unusual thoughts, aggressive reaction, apathy, increased appetite, decreased libido, delusions, dementia, speech disturbances, altered self-perception, strange feeling, movement disorders, hypotonia, hysteria, intoxicated feeling, manic reaction, neuropathic 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 bleeding, dental caries, anemia, high levels of hemoglobin, decreased white blood cell count, enlarged lymph node, macrocytic anemia, purpura (patch-shaped rash), thrombosis, abscess, herpes, shingles, middle or outer ear infection, increased bilirubin levels, increased liver enzyme levels, gout, high cholesterol or lipid levels in the blood, kidney function disorders, periocular edema, joint disease, muscle weakness, pain radiating to the leg, tendinitis, breast tumors, breast pain, bronchospasm, respiratory depression, nosebleed, reduced blood oxygen, throat inflammation, pneumonia, acne, rash with blisters, dermatitis, pustular rash, photosensitivity, urticaria, conjunctivitis, corneal ulceration, lacrimation disorders, smell identification disturbance, light flashes, severe kidney failure, painful or frequent urination, nocturia, polyuria, kidney inflammation, kidney pain, urinary retention.
Side effects of unknown frequency (effects whose frequency has not been determined yet):
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 with the doctor.
Side effects can be reported to the Ministry of Health by clicking 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
Additionally, you can report to "Unipharm Ltd."

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 below 25°C, in a place that is protected from light.

6. FURTHER INFORMATION:

In addition to the active ingredient, the medicine also contains:
Lactose (anhydrous), microcrystalline cellulose, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate, opadry white Y-1-7000.
Each **Zodorm 10** tablet contains 90 mg lactose.
What the medicine looks like and contents of the package:
Zodorm 10 is packed in trays (blisters) inserted into a carton package.
Each package of **Zodorm 10** contains 2, 6, 10, 15, 20 or 30 tablets. Not all package sizes may be marketed.
Zodorm 10 tablets are round, biconvex and white-colored with a score line on one side.
Registration holder and address: Unipharm Ltd., P.O. Box 21429, Tel Aviv, 6121301.
Manufacturer and address: Unipharm Ltd., "Mevo Carmel" Industrial Park.
Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Zodorm 10: 123 62 30320 01
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