PACKAGE LEAFLET: INFORMATION FOR THE USER

Stilnox® 10 mg scored film-coated tablet

zolpidem tartrate

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 STILNOX IS AND WHAT IT IS USED FOR

This medicine belongs to a group of medicines called benzodiazepines.
It is used as short-term treatment for insomnia in adults.
Due to a lack of data, the use of this medicine is not recommended in children and adolescents under 18 years of age.

2. WHAT DO YOU NEED TO KNOW BEFORE YOU TAKE STILNOX

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Contraindications:
Do not take Stilnox:

- if you are allergic to the active substance, the family of medicines that belong to the benzodiazepine group or any of other ingredients of this medicine (listed in section 6).
- if you have serious respiratory failure.
- if you have a serious liver disease (serious liver failure).
- if you have sleep apnoea syndrome (condition where you stop breathing for short periods in your sleep).
- if you have myasthenia (muscle disease).
- over a long period of time. Treatment should be as short as possible, because the risk of dependence increases with the duration of treatment.
- if you have ever had episodes of sleepwalking or any other unusual behaviour while sleeping (such as driving, eating, making a phone call or having sex, etc.) without being fully awake after taking Stilnox or other medicines containing zolpidem.

Warnings and precautions
Talk to your doctor or pharmacist before taking Stilnox.

Risk of ABUSE, DEPENDENCE and WITHDRAWAL SYNDROME

Please tell your doctor or pharmacist if you have ever suffered from psychiatric disorders or if you have ever abused or had a dependence on alcohol, medicines or drugs.

Do not use Stilnox over a long period of time. Treatment should be as short as possible.

Taking this type of medicine can cause drug abuse and physical and psychological dependence, especially if taken for long periods (these effects are caused by the patient's urge to take the medicine).

The risk of dependence increases with the dose and duration of treatment. Cases of dependence have been reported more frequently in patients treated with Stilnox for more than 4 weeks. The risk of dependence also increases if you have a history of mental disorders, and/or if you have a history of alcohol, illicit substance or drug abuse or dependence.

Dependence can occur even without these predisposing factors.

If the medicine becomes less effective following repeated use, do not increase the dose.

For more information, talk to your doctor or pharmacist.

Stopping this treatment SUDDENLY can cause the development of WITHDRAWAL effects. This is characterized by the onset, within a few hours or days, of signs such as severe anxiety, insomnia and aching muscles, but restlessness, irritability, headaches, numbness or tingling in your hands and feet, being more sensitive than normal to noise, light or touch, etc. may also be observed.

The conditions for stopping treatment should be defined with your doctor.

The best way to prevent these withdrawal effects is to very GRADUALLY reduce doses and increase the interval between doses. This tapering-off period will be longer if you have been taking the treatment for a long time.

Risk of REBOUND EFFECT

Despite gradually reducing the doses, a REBOUND effect, which is not serious, may occur, with the TEMPORARY reappearance of the symptoms (insomnia) that led to starting treatment in the first place.

Memory loss

Memory loss may occur in the first few hours after taking the medicine.
During the hours that follow, you may have difficulty in coordinating certain movements (psychomotor impairment), including driving ability, may be increased if:

- you take this medicine less than 8 hours before performing activities that require your alertness,
- you take a higher dose than the recommended dose,
- you take zolpidem while you are already taking another central nervous system depressants or another medicine that increases the amount of Stilnox in the blood, or while drinking alcohol, or while taking illicit substances.

To reduce these risks, you should take the medicine as a single intake immediately at bedtime (see section 3. "How to take Stilnox"), ensure that conditions are as conducive as possible to several hours of uninterrupted sleep and not take another dose during the same night.

Adverse reactions, sleepwalking and unusual sleeping behaviour

In some people, this medicine may cause reactions that are contrary to those sought: insomnia, nightmares, restlessness, nervousness, euphoria or irritability, tension, changes in consciousness, or even potentially dangerous behaviour (aggressiveness against themselves or towards those around them, as well as behavioural disturbances and automatic acts).

Stilnox may cause sleepwalking or other unusual behaviour while sleeping (such as driving, eating, making a phone call or having sex, etc.) without being fully awake. The next morning you may not remember what you did during the night. If you experience any of the above situations, stop treatment with Stilnox immediately and contact your doctor or pharmacist as this sleep behaviour may pose a risk of serious injury to yourself or those around you.

Drinking alcohol or taking other medicines that may make you drowsy with Stilnox may increase the occurrence of these sleep behaviours.

Use in elderly patients
Benzodiazepines and related drugs should be used with caution in elderly people, since there is a risk of drowsiness and/or muscle-relaxant effects which may promote falls, often with serious consequences in this population.

Use in patients with severe liver failure
Do not take Stilnox if you have severe liver failure due to the potential risk of inflammatory brain disease (encephalopathy).

Other warnings and precautions
This medicine alone cannot resolve the causes of sleep problems. You should ask your doctor for advice. He/she will advise you on measures you can take to improve your sleep.

Close medical monitoring is necessary while taking this medicine, especially if you have chronic liver disease, alcoholism or respiratory failure.

Insomnia may be a sign of another physical or psychiatric disorder.

If the insomnia persists or gets worse after a short period of treatment, see your doctor.

This medicine does not treat depression. In people with depression, it should not be used alone since it would allow the depression to progress independently, with a persistent or enhanced risk of suicide.

Some studies showed an accumulated risk of suicidal ideation, suicide attempts and suicide in patients taking some sedatives and hypnotics, including this medicinal product. It has not, however, been established if this was caused by this medicine or for other reasons. If you experience suicidal ideation, contact your doctor as soon as possible to obtain medical advice.

Intake of alcohol is strictly inadvisable throughout the duration of treatment.

Other medicines and Stilnox
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
While taking Stilnox with the following medicines, drowsiness, and next-day psychomotor impairment effects, including impairment of the ability to drive and use machines, may be increased.
- medicines for some mental health problems (antipsychotics),
- medicines for sleep problems (hypnotics),
- medicines to calm or reduce anxiety,
- medicines for depression,

- medicines for moderate to severe pain (narcotic analgesics),
- medicines for epilepsy,
- medicines used for anaesthesia,
- medicines for hay fever, rashes or other allergies that can make you sleepy (sedative antihistamines).

While taking Stilnox with antidepressants including bupropion, fluoxetine, sertraline and venlafaxine, you may see, hear or feel things that are not real (hallucinations). It is not recommended to take Stilnox with fluvoxamine, ciprofloxacin and/or St. John's Wort.

Concomitant use of Stilnox and opioids (strong analgesics, replacement therapy and certain cough medicines) increases the risk of drowsiness, difficulty breathing (respiratory depression), coma and can be life-threatening. Therefore, concomitant use should only be considered when no alternative treatment can be used.

However, if you are prescribed Stilnox in combination with opioids, your doctor must limit the dose and duration of the concomitant treatment.

Inform your doctor of any opioids you are currently taking and closely follow the dosage recommended by your doctor. You may want to tell your friends and family of the signs and symptoms mentioned above.

Contact your doctor if these symptoms occur.

Stilnox with food and drink
Intake of alcohol is strictly inadvisable throughout the duration of treatment.

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.

Pregnancy
Use of this medicine is not recommended during pregnancy. If you discover that you are pregnant or are planning to have a baby, consult your doctor who will re-assess the need for treatment.

If you take Stilnox during the first trimester of pregnancy, although extensive data have not demonstrated any malformative effect with benzodiazepines, some studies have shown a potentially increased risk of cleft lip and palate in newborn babies compared to that in the general population. Cleft lip and palate (sometimes called "harelip") is a deformation at birth caused by incomplete fusion of the palate and upper lip. According to these data, the incidence of cleft lip and palate would appear to be less than 2 per 1000 in newborns exposed to benzodiazepines during pregnancy, compared to an expected ratio of 1 per 1000 in the general population.

Reduced foetal movement and foetal heart rate variability may occur after taking Stilnox during the second and/or third trimester of pregnancy.

If you take Stilnox at the end of your pregnancy, tell the medical staff. Your newborn baby may need to be monitored. Muscle weakness (axial hypotonia), difficulty feeding (problems suckling causing poor weight gain), overexcitability, agitation or trembling may occur in the newborn baby. These problems are reversible. At high doses, respiratory failure or apnoea, or a drop in body temperature (hypothermia) could also occur in the newborn baby.

If your baby has any of these symptoms at birth or afterwards, contact your doctor and/or midwife.

Breast-feeding
This medicine passes into breast milk; breast-feeding is therefore inadvisable.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Stilnox may affect your ability to drive and use machines, with a risk of “sleep driving”. On the day after taking Stilnox (as other hypnotic medicines), you should be aware that:

- you may feel drowsy, sleepy, dizzy or confused,
- your quick decision-making may be longer,
- your vision may be blurred or double,
- you may be less alert.

A period of at least 8 hours is recommended between taking Stilnox and driving, using machinery and working at heights to minimize the above listed effects.

Do not drink alcohol or take medicines containing alcohol, or take other medicines used to treat some mood or behavioural problems (antipsychotics) while you are taking Stilnox, as this can increase the above listed effects.

Stilnox contain lactose and sodium
This medicine contains lactose. It is not recommended in patients with galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption (rare hereditary diseases).

This medicine contains less than 1 mmol (23 mg) sodium per tablet, that is to say essentially “sodium-free”.

3. HOW TO TAKE STILNOX

Dosage
The dosage is determined strictly on a case-by-case basis and the usual doses may vary.

The recommended dose per 24 hours is 10 mg of Stilnox. A lower dose may be prescribed to some patients.

In all cases, your doctor will try to find the lowest possible dose that suits you.

Do not exceed a dose of 10 mg per day.

Due to a lack of data, the use of this medicine is not recommended in children and adolescents under 18 years of age.

Always take this medicine exactly as your doctor has told you.

Method of administration
Oral use

Frequency of administration

Take this medicine as a single daily intake just before bedtime.

Make sure you have a period of at least 8 hours after taking this medicine before performing activities that require your alertness.

Duration of treatment
The duration of treatment should be as short as possible and should not exceed 4 weeks (see section 2, paragraph "Warnings and precautions").

If the insomnia persists, see your doctor.

If you take more Stilnox than you should:
Consult your doctor or pharmacist immediately.

If you forget to take Stilnox:
Take the next dose at the usual time on the following day. Do not take a double dose to make up for a forgotten dose.

If you stop taking Stilnox:
Withdrawal and rebound phenomena (see section 2, paragraph "Warnings and Precautions").

4. POSSIBLE SIDE EFFECTS

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

They depend on the dose you take and your individual sensitivity.

The following side effects are common (affecting 1 to 10 patients in 100):
- hallucinations.
- restlessness,
- nightmares,
- depression,
- impaired alertness or even drowsiness (particularly in the elderly),
- headache,
- giddiness,
- insomnia,
- memory loss concerning events that occurred during treatment (anterograde amnesia) with abnormal behaviour. This effect may occur at the doses prescribed by your doctor. The risk increases proportionally to the dose,
- diarrhoea,
- nausea,
- vomiting,
- abdominal pain,
- respiratory tract infections,
- feeling tired.

The following side effects are uncommon (affecting 1 to 10 patients in 1 000):
- confusion,
- irritability,
- nervousness,
- aggressiveness,
- sleepwalking or other unusual behaviour while sleeping (such as driving, eating, making a phone call or having sex, etc.) without being fully awake (see section 2 paragraph "Warnings and precautions"),
- excitement (euphoric mood),
- tingling sensation in the hands and feet (paraesthesia),
- tremors,
- attention and speech disorders,
- double vision,
- blurred vision,
- elevated liver enzymes,

- appetite disorders,
- skin rash and itching, joint pain,
- muscle pain, muscle spasm and muscle weakness.

The following side effects are rare (1 patient in 10 000):
- libido disorders,
- consciousness disorders,
- vision problems (visual impairment),
- liver damage,
- red itchy blotches on the skin (hives),
- balance disorders, falls.

The following side effects are very rare (fewer than 1 patient in 10 000):
- physical and psychological dependence, even at doses recommended by your doctor, withdrawal symptoms or rebound insomnia that may occur on stopping treatment (see section 2 “Warnings and precautions”),
- difficulty breathing.

The following side effects may occur but their frequency is not known:
- sudden swelling of the face and/or neck that can lead to difficulty breathing and be life threatening (angioedema),
- behavioural disturbances,
- anger,
- difficulty in coordinating certain movements,
- tension,
- delirium (a sudden and severe change in mental state that causes a person to appear confused or disoriented).

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.
By reporting side affects you can help provide more information on the safety of this medicine.

5. HOW TO STORE STILNOX

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 after EXP {MM/YYYY}. The expiry date refers to the last day of that month.

Store below 30ºC.

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 Stilnox 10 mg scored film-coated tablets contain

- The active substance is:
  Zolpidem tartrate ..... 10 mg

For one scored film-coated tablet.

- The other ingredients are:

  Core:
  Lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, hypromellose, magnesium stearate.

  Film-coating:
  Hypromellose, titanium dioxide suspension, macrogol 400.

What Stilnox 10 mg scored film-coated tablets look like and contents of the pack
This medicine is a scored film-coated tablet.
Box of 7, 14, 20, 21, 28, 50, 100 or 150.
Bottle of 20 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
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Manufacturer
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