

# Stilnox® 10 mg, scored film-coated tablets

zolpidem

## Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions or are unsure of anything, ask your doctor or pharmacist for more information.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects become serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## What is in this leaflet :

1. What Stilnox is and what it is used for
2. What you need to know before you take Stilnox
3. How to take Stilnox
4. Possible side effects
5. How to store Stilnox
6. Contents of the pack and other information.

## 1. WHAT STILNOX IS AND WHAT IT IS USED FOR

### Hypnotics and sedatives

This medicine is related to benzodiazepines.

It is used to treat 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 YOU NEED TO KNOW BEFORE YOU TAKE STILNOX

If you have been told by your doctor that you are intolerant to some sugars, contact him/her before taking this medicine.

### Contraindications:

#### Do not take Stilnox in the following situations:

- If you are allergic to the active substance (zolpidem) or any of the other ingredients of Stilnox. See section 6 for a list of ingredients.
- If you have serious respiratory failure.
- If you have a serious liver disease (serious liver failure).
- If you have sleep apnea syndrome (condition in which you stop breathing for short periods in your sleep).
- If you have myasthenia (muscle disease).

### Appropriate precautions for use: Special warnings:

#### Take special care with Stilnox:

##### Before you take Stilnox, inform your doctor:

- if you have respiratory failure,
- if you have a liver disease (liver failure),
- if you have ever had problems with alcohol dependence.

##### Before you take Stilnox tablets, you should be aware of the following:

Insomnia may be a sign of another physical or psychological disorder. A medical evaluation must be performed before prescribing this medicine.

This medicine does not treat depression. If you also have depression, your doctor will prescribe a suitable treatment for you. If depression is not treated, it can worsen and the risk of suicide may increase or persist.

Consult your doctor if your insomnia persists or worsens after a short period of treatment.

The following may occur during the hours after you take this medicine:

- memory loss concerning events that occurred during treatment (anterograde amnesia),
- behavioral disturbances (such as aggressiveness or automatic acts),
- impaired consciousness,
- difficulty coordinating certain movements (impaired psychomotor function), impaired driving ability, especially if:
  - you take this medicine less than 8 hours before performing activities that require you to be alert,
  - you take a higher dose than the recommended dose,
  - you take zolpidem while you are already taking another sedative or other medicines that increase the amount of Stilnox in the blood, or alcoholic drinks or medicines containing alcohol, or illicit substances.

Take the Stilnox tablet as a single dose just before going to bed.

Do not take another dose during the course of the same night.

These disorders can be dangerous for you or for other people. If these disorders occur, you must stop taking the treatment.

The following may also occur:

- sleepwalking,

- driving a car without being completely awake and with memory loss concerning the events that occurred.

Misuse of Stilnox and simultaneous use of alcohol or other medicines that affect your alertness appear to increase the risk of these behaviors. In these cases, you should stop taking the treatment.

### Risk of dependence

This medicine can cause physical and psychological dependence.

Dependence can result in a withdrawal syndrome which may include the following symptoms: insomnia, headache, anxiety, muscle pain, irritability, confusion, hallucinations or seizures.

It can occur during treatment between 2 doses or during the days after you stop taking the treatment.

Various factors appear to promote dependence:

- if you take Stilnox for long periods of time,
- if you take a high dose,
- if you have ever been addicted to other medicines, substances or alcohol,
- if you are taking another medicine in the benzodiazepine group, such as an anxiety medicine or another sleeping medicine.

Read section 3 "How to take Stilnox" carefully. For more information, consult your doctor or pharmacist.

### Risk of rebound effect

Insomnia can recur temporarily after stopping treatment.

In order to reduce the risk of a withdrawal syndrome or rebound insomnia, the dose will be gradually reduced and the doses spaced out. You should discuss how to stop treatment with your doctor.

### Use in elderly patients over 65 years of age

Stilnox should be used with caution in elderly patients due to a higher frequency of behavioral disturbances, the risk of drowsiness, and the risk of muscle relaxation effects that can promote falls. Falls often have serious consequences in the elderly.

### Other medicines and Stilnox

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you take Stilnox with the following treatments, this could increase drowsiness and next-day coordination difficulties, as well as impaired ability to drive and use machines:

- medicines for some mood and behavioral 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 asthma,
- medicines for hay fever or other allergies that can make you sleepy (sedative antihistamines).

If you take Stilnox with antidepressants including bupropion, fluoxetine, sertraline and venlafaxine, you may see, hear or feel things that are not real (hallucinations).

Taking zolpidem with fluvoxamine or ciprofloxacin is not recommended.

### Food and drink

You are strongly advised not to consume alcohol while taking this medicine.

### Pregnancy

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

Use of Stilnox during pregnancy is not recommended. If you discover that you are pregnant, consult your doctor. Only your doctor can decide whether or not it is necessary to continue treatment.

### Breast-feeding

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

This medicine passes into breast milk. Breast-feeding is therefore not recommended.

### Driving and using machines

Stilnox may have an influence on your ability to drive and use machines, with a risk of falling asleep while driving. On the day after taking Stilnox (as with other hypnotic medicines), you should be aware that:

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

To minimize these effects, you should sleep for at least 8 hours between taking zolpidem and driving, using machinery and working at heights.

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

### Important information about some of the ingredients of Stilnox

This medicine contains a sugar (lactose) that is broken down into galactose and glucose. You should not take this medicine if you have galactose intolerance, Lapp lactase deficiency or glucose/galactose malabsorption syndrome (rare hereditary diseases).

### 3. HOW TO TAKE STILNOX

#### Dosage

Always take the dose prescribed by your doctor. If you are unsure of anything, consult your doctor or pharmacist. Due to a lack of data, the use of Stilnox is not recommended in children and adolescents under 18 years of age.

The recommended dose for Stilnox is 10 mg per day. However, you may be prescribed a lower dose.

Your doctor will always try to find the lowest effective dose for you.

Never exceed a dose of 1 tablet per day.

If you are older than 65 years of age, the recommended dose is 5 mg per day. If you have a liver disease (liver failure), the recommended starting dose is 5 mg per day. If you have the impression that this medicine is less effective over time, do not increase the dose. Consult your doctor.

#### Method of administration

This medicine is taken by mouth. Swallow the tablet with a glass of water. The tablets are scored, which means you can break them into 2 equal halves if necessary.

#### Frequency of administration

Take this medicine in bed as a single daily dose just before going to sleep.

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

This will make it possible to limit the risk of memory loss (amnesia) and difficulty coordinating certain movements (impaired psychomotor function).

#### Treatment duration

Treatment duration should be as short as possible and should not exceed 4 weeks (see section "Take special care with Stilnox"), including the dose reduction period.

If the insomnia persists, see your doctor.

#### If you take more Stilnox than you should:

Consult your doctor, a pharmacist or an emergency service immediately, as overdose can be dangerous.

#### 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:

Suddenly stopping this treatment may cause a withdrawal syndrome.

When the decision to stop taking Stilnox has been made, your doctor must tell you how to stop your treatment.

To minimize withdrawal symptoms or rebound insomnia, your doctor will gradually reduce your doses and space them out. The dose reduction period will be longer if the treatment has been taken for a long time.

Rebound effects can occur despite gradual dose reduction. If this happens, the insomnia that you were treated for may recur temporarily.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Stilnox 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):

- restlessness,
- nightmares,
- hallucinations,
- impaired alertness or even drowsiness (particularly in the elderly),
- insomnia,
- lightheadedness,
- headache,
- memory loss concerning events that occurred during treatment (anterograde amnesia). This can occur even at doses prescribed by your doctor, and the risk increases proportionally with the dose,
- diarrhea,
- nausea,
- vomiting,
- abdominal pain,
- feeling tired,
- respiratory tract infections.

#### ► The following side effects are uncommon (affecting 1 to 10 patients in 1 000):

- confusion,
- irritability,
- double vision.

#### ► 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),
- behavioral disturbances,
- impaired consciousness,
- aggressiveness,
- nervousness,
- delusion,
- anger,
- sleepwalking,
- physical and psychological dependence, even at doses recommended by your doctor, withdrawal symptoms or rebound insomnia on stopping treatment (see also sections "Risk of dependence" and "Risk of rebound effect"),
- depression,
- changes in libido,
- difficulty coordinating certain movements,
- tension,
- difficulty breathing,
- skin rashes,
- itching,
- red, itchy patches on the skin (hives),
- muscle weakness,
- falls,
- elevated liver enzymes.

#### 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 effects 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 Stilnox after the expiry date which is stated on the box or bottle.

Store below 25°C.

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:

Tablet core: lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, magnesium stearate.

Film-coating: hypromellose, titanium dioxide, macrogol 400.

#### What Stilnox 10 mg scored film-coated tablets look like and contents of the pack

This medicine is supplied as scored film-coated tablets in a box or bottle.

Each box contains 7, 14, 20, 21, 28, 50, 100 or 150 scored film-coated tablets. Each bottle contains 20 or 100 scored film-coated tablets.

Not all pack sizes may be marketed in your country.

#### Marketing Authorization Holder

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82, avenue Raspail - 94250 Gentilly - France

#### Manufacturer

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