

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Stilnoct 5mg Film-coated Tablets

zolpidem tartrate

SANOFI 



Is this leaflet hard to see or read?
Phone 0845 372 7101 for help

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, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Stilnoct is and what it is used for



The name of your medicine is Stilnoct 5mg Film-Coated Tablets (called Stilnoct in this leaflet). Stilnoct contains a medicine called zolpidem tartrate. This belongs to a group of medicines called hypnotics. It works by acting on your brain to help you sleep.

Stilnoct is used for temporary sleep problems in adults that are causing you severe distress or that are affecting your everyday life. This includes sleep problems in adults such as:

- Difficulty falling asleep
- Waking in the middle of the night
- Waking too early

Your doctor will identify your sleep problem wherever possible and the underlying factors before prescribing this medicine for you. The failure of your sleep problems to stop after a 7-14 day course of treatment may indicate you have an underlying disorder, your doctor will assess you at regular intervals.

Stilnoct is not meant to be used every day for long periods of time. Ask your doctor for advice if you are unsure.

2. Before you take Stilnoct



Do not take this medicine and tell your doctor if:

- × You are allergic (hypersensitive) to zolpidem tartrate or any of the other ingredients of Stilnoct (listed in section 6 below)
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- × Your lungs do not work properly (respiratory failure)
- × You have severe liver problems
- × You have a problem where you stop breathing for short periods at night (sleep apnoea)
- × You have a problem that causes severe muscle weakness (myasthenia gravis)
- × You have been told by a doctor that you have a mental illness (psychosis)
- × You are under the age of 18

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Stilnoct.



Take special care with Stilnoct Check with your doctor or pharmacist before taking your medicine if:

- ▲ You have a history of alcohol or drug abuse
- ▲ You have liver problems
- ▲ You have depression or have had another mental illness in the past
- ▲ You have recently taken Stilnoct or other similar medicines for more than four weeks
- ▲ You are elderly

Stilnoct can cause drowsiness and decrease your level of alertness. This could cause you to fall, sometimes leading to severe injuries.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Stilnoct.

Next-day psychomotor impairment (see also Driving and using machines)

The day after taking Stilnoct, the risk of psychomotor impairment, including impaired 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 Stilnoct while you are already taking other central nervous system depressants or another medicine that increases Stilnoct in your blood, or while drinking alcohol, or while taking illicit substances

Take the single intake immediately at bedtime. Do not take another dose during the same night.

Turn
Over



Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Stilnoct can affect the way some other medicines work. Also some medicines can affect the way Stilnoct works.

Tell your doctor if you are taking any of the following medicines:

Stilnoct may increase the effect of the following medicines:

While taking Stilnoct with the following medicines, drowsiness and next-day psychomotor impairment effects, including impaired driving ability, 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 Stilnoct with antidepressants including bupropion, desipramine, fluoxetine, sertraline and venlafaxine, you may see things that are not real (hallucinations).

It is not recommended to take Stilnoct with fluvoxamine, ciprofloxacin or St John's Wort (a herbal medicine) used for mood swings and depression.

The following medicines can increase the chance of you getting side effects when taken with Stilnoct. To make this less likely, your doctor may decide to lower your dose of Stilnoct:

- Some antibiotics such as clarithromycin or erythromycin
- Some medicines for fungal infections such as ketoconazole and itraconazole
- Ritonavir (a protease inhibitor) – for HIV infections

The following medicines can make Stilnoct work less well:

- Some medicines for epilepsy such as carbamazepine, phenobarbital or phenytoin
- Rifampicin (an antibiotic) - for infections

Taking Stilnoct with food and drink

- **Do not drink alcohol** while you are taking Stilnoct. Alcohol can increase the effects of Stilnoct and make you sleep very deeply so that you do not breathe properly or have difficulty waking.

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant, or think you may be pregnant. Taking Stilnoct during pregnancy may harm your baby.

You should not breast-feed if you are taking Stilnoct. This is because small amounts may pass into mother's milk.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.



Driving and using machines

Stilnoct has major influence on the ability to drive and use machines such as "sleep driving". On the day after taking Stilnoct (as with 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 Stilnoct and driving, using machinery and working at heights to minimize the above listed effects.

Do not drink alcohol or take other psychoactive substances while you are taking Stilnoct as it can increase the above listed effects.

Important information about some of the ingredients of Stilnoct

Stilnoct contains:

Lactose: This is a type of sugar. If you have been told by your doctor that you cannot tolerate some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

3. How to take Stilnoct

Always take Stilnoct exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- Swallow the tablet whole with a drink of water
- The recommended dose per 24 hours is 10mg of Stilnoct. A lower dose may be prescribed to some patients.
- Stilnoct should be taken as a single 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.
- Do not exceed 10mg per 24 hours.
- The usual length of treatment is 2 days to 4 weeks.

Adults

The usual dose is two Stilnoct tablets (10mg) just before bedtime.

Elderly

The usual dose is one tablet (5mg) just before bedtime.

Patients with liver problems

The usual starting dose is one tablet (5mg) just before bedtime. Your doctor may decide to increase this to two tablets (10mg) if it is safe to do so.

Children and adolescents

Stilnoct should not be used in people under 18 years old.

If you take more Stilnoct than you should

If you take more Stilnoct than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken.

Taking too much Stilnoct can be very dangerous. The following effects may happen:

- Feeling drowsy, confused, sleeping deeply and possibly falling into a fatal coma.

If you forget to take Stilnoct

Stilnoct must only be taken at bedtime. If you forget to take your tablet at bedtime, then you should not take it at any other time, otherwise you may feel drowsy, dizzy and confused during the day.

Do not take a double dose to make up for a forgotten tablet.

If you stop taking Stilnoct

Keep taking Stilnoct until your doctor tells you to stop. Do not stop taking Stilnoct suddenly, but tell your doctor if you want to stop. Your doctor will need to lower your dose and stop your tablets over a period of time.

If you stop taking Stilnoct suddenly, your sleep problems may come back and you may get a 'withdrawal effect'. If this happens you may get some of the effects listed below.

See a doctor straight away if you get any of the following effects:

- Feeling anxious, restless, irritable or confused
 - Headache
 - Faster heartbeat or uneven heartbeat (palpitations)
 - Nightmares, seeing or hearing things that are not real (hallucinations)
 - Being more sensitive to light, noise and touch than normal
 - Relaxed grip on reality
 - Feeling distant from your body or feeling 'puppet-like'
 - Numbness and tingling in your hands and feet
 - Aching muscles
 - Stomach problems
 - Sleep problems come back worse than before
- In rare cases fits (seizures) may also occur.

4. Possible side effects

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

Stop taking Stilnoct and see a doctor or go to a hospital straight away if:

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Tell your doctor as soon as possible if you have any of the following side effects:

Common (affects less than 1 in 10 people)

- Poor memory while taking Stilnoct (amnesia) and strange behaviour during this time. This is more likely to affect you in the few hours after you take this medicine. By having 7-8 hours sleep after taking Stilnoct, this is less likely to cause you a problem.
- Sleeping problems that get worse after taking this medicine
- Seeing or hearing things that are not real (hallucinations)

Uncommon (affects less than 1 in 100 people)

- Blurred eyesight or 'seeing double'

Frequency unknown

- Being less aware of your environment
- Falling, especially in the elderly

Sleep-Driving and other strange behaviour

There have been some reports of people doing things while asleep that they do not remember when waking up after taking a sleeping medicine. This includes sleep-driving, sleep walking, preparing and eating food, and having sex. Alcohol and some medicines for depression or anxiety can increase the chance that this serious effect will happen.

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

Common (affects less than 1 in 10 people)

- Diarrhoea
- Feeling sick (nausea) or being sick (vomiting)
- Abdominal pain
- Respiratory infection
- Headache
- Feeling tired or agitated
- Nightmares

- A feeling of being out of touch with reality and being unable to think or judge clearly (psychosis)
- Feeling dizzy
- Feeling drowsy or sleepy
- Back pain

Uncommon (affects less than 1 in 100 people)

- Feeling confused or irritable
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)
- Tremor
- Blurred vision
- Changes in appetite or behaviour concerning appetite
- Muscle pain
- Muscle spasms

Very rare (affects less than 1 in 10,000 people)

- Any changes of vision, in particular loss of vision

Frequency unknown

- Itching skin or skin rash
- Excessive sweating
- Slower breathing (respiratory depression)
- Weak muscles
- Feeling restless, aggressive, angry or showing unusual behaviour
- Depression
- Feeling overly happy/confident (euphoric)
- Thinking things that are not true (delusions)
- Changes in sex drive (libido)
- Changes in the amount of liver enzymes – shown up in the results of blood tests
- You have discolouration of the skin or eyes, pain in the abdomen (stomach) or a bloated feeling, severe itching, pale or bloody stools, extreme weakness, nausea or loss of appetite. This could be caused by an infection or injury to the liver

- An illness where removal of bile from the liver is blocked (cholestasis). Signs include jaundice, rash or fever and the colour of your water (urine) becomes darker
- Lack of concentration
- Speech problems
- Changes in the way you walk
- Stilnoct having less effect than normal
- Becoming dependent on Stilnoct

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Stilnoct

Store below 30°C. Keep the blister strip in the carton in order to protect from moisture.

Keep this medicine in a safe place where children cannot see or reach it.

Do not use Stilnoct after the expiry date which is stated on the carton or blister after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Stilnoct contains

- Each tablet of Stilnoct contains 5mg of the active substance zolpidem tartrate

- Other ingredients are lactose monohydrate, microcrystalline cellulose, hypromellose, titanium dioxide (E171), sodium starch glycolate, magnesium stearate and macrogol 400.

What Stilnoct looks like and contents of the pack

Stilnoct is a round, white, film-coated tablet contained within PVC/ foil blisters in cartons containing 4, 14, 28, or 56 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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