INFORMATION FOR PATIENTS
Stilnoct® 5mg Film-Coated Tablets and
Stilnoct® 10mg Film-Coated Tablets
zolpidem tartrate

Is this leaflet hard to see or read?
Phone 01 403 5600 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 side effects gets serious, or if you notice any side effect not listed in this
  leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What Stilnoct is and what it is used for
2. What you need to know before you are given Stilnoct
3. How to take Stilnoct
4. Possible side effects
5. How to store Stilnoct
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1. What Stilnoct is and what it is used for

The name of your medicine is Stilnoct. The tablets come in two strengths: Stilnoct
5mg Tablets and Stilnoct 10mg Tablets.
Zolpidem tartrate 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 severe
distress or that are affecting every day life.
This includes sleep problems such as:
• Difficulty falling asleep
• Waking in the middle of the night
• Waking too early
Stilnoct is not meant to be used every day for long periods of time. Ask your doctor
for advice if you are unsure.

2. What you need to know before you are given Stilnoct

Do not take Stilnoct if :
• You are allergic (hypersensitive) to zolpidem tartrate or any of the other ingredients
  (listed in section 6 below). Signs of an allergic reaction include: 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 are under 18 years of age
Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist.

**Warnings and precautions**
Check with your doctor or pharmacist before taking this medicine if:
- 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 your doctor that you have a mental illness (psychosis)
- 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 or have ever had thoughts of harming or killing yourself
- You have recently taken Stilnoct or other similar medicines for more than four weeks
- You are elderly
- You have ever had any heart problems including slow or uneven heartbeat
- Stilnoct can cause drowsiness and decrease your level of alertness. This could cause you to fall, sometimes leading to severe injuries.

**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 another central nervous system depressants or another medicines that increase 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.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Stilnoct.
If following a 7-14 day course of treatment, symptoms persist, contact your doctor so that your treatment can be re evaluated

**Other medicines and Stilnoct**
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:**
While taking Stilnoct with the following medicines, drowsiness and next day psychomotor impairment effects, including 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 depressions
• Medicines for moderate to severe pain (narcotic analgesics)
• Medicines for epilepsy
• Medicines used in anesthesia
• 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 or ciprofloxacin.

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
• St John's Wort (a herbal medicine) – for mood swings and depression –use of Stilnoct and St John’s Wort is not recommended.

Taking Stilnoct with food and drink
Do not drink alcohol while you are being treated with 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 or intend to become pregnant or think you might 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 advise 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 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.

For more information about possible side effects which could affect your driving see section 4 of this leaflet.

**Important information about some of the ingredients of Stilnoct**

Stilnoct contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### 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 10 mg 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 one 10mg Stilnoct tablet just before bedtime.

**Elderly**

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

**Patients with liver problems**

The usual starting dose is one 5mg Stilnoct tablet just before bedtime. Your doctor may decide to increase this to one 10mg Stilnoct tablet 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)
• Memory disorders such as poor memory (amnesia), memory impairment, inability to recall the recent past (anterograde amnesia). 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)
• Drowsiness or a strong desire to sleep
• Dizziness

Uncommon (affects less than 1 in 100 people)
• Blurred eyesight or ‘seeing double’
• Change in appetite (appetite disorder)

Rare

Reference: 7629 1.3.2.1 - Mock-up Leaflet - PIL - 10mg - 2017-06-15 - 0000 - RTQ CCDS V11 only PIL - 540/160/2 5.1
• Decreased ability to see (visual impairment)

**Frequency unknown**
• Being less aware of your environment
• Falling, especially in the elderly
• Feeling of intense elation or confidence (euphoria)

**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 sleep medicine. This includes sleep-driving, sleep walking 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
• Infection of the lungs or airways (respiratory infection)
• Headache
• Feeling tired or agitated
• Nightmares
• Back pain

**Uncommon** (affects less than 1 in 100 people)
• Feeling confused or irritable
• Pains in your joints or muscles, muscle spasms
• Neck pain
• Unusual sensation or tingling of skin
• Tremor

**Frequency unknown**
• Itching skin or skin rash
• Excessive sweating
• Slower breathing (respiratory depression)
• Weak muscles
• Feeling restless, aggressive, angry or showing unusual behaviour
• Depression
• Thinking things that are not true (delusions)
• Changes in sex drive (libido)
• Change in the amount of liver enzymes – shown up in the results of blood tests
• Changes in the way you walk
• Stilnox having less effect than normal
• Disturbance in attention
• Speech difficulties

**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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie E-mail: medsafty@hprai.e
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Stilnoct
Keep Stilnoct out of the reach and sight of children. Do not store Stilnoct 5mg Film-Coated Tablets above 25°C. Keep blister in the outer carton in order to protect from light. There is no special storage conditions for Stilnoct 10mg Film-Coated Tablets. Do not take this medicine after the expiry date shown on the blister and carton. Only use them at the time when your doctor prescribed them. If you have any left over take them back to a pharmacist.
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
Stilnoct 5 mg Film-Coated Tablets contain 5 mg zolpidem tartrate.
Stilnoct 10 mg Film-Coated tablets contain 10 mg zolpidem tartrate.
The film-coated tablets also contain lactose, magnesium stearate, hypromellose, microcrystalline cellulose, macrogol 400, sodium starch glycollate, titanium dioxide (E171).

What Stilnoct looks like and contents of the pack
Stilnoct 5mg Tablets are round, white, filmcoated tablets.
Stilnoct 10mg Tablets are oblong, white, film-coated scored tablet engraved SN10.
Stilnoct 5mg Film-Coated Tablets and Stilnoct 10mg Film-Coated Tablets are available in packs of 28 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Sanofi-aventis Ireland Limited T/A SANOFI
Citywest Business Campus
Dublin 24.
Tel: 01 403 5600
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Manufacturer:
Stilnoct 5mg Film-Coated Tablets are manufactured by:
Sanofi Winthrop Industrie,
30 – 36 Avenue Gustave Eiffel,
37000 Tours, France.

Stilnoct 10mg Film-Coated Tablets are manufactured by:
Delpharm Dijon,
6, Boulevard de l'Europe,
21800 Quétigny, France.

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Stilnoct is a registered trademark.

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