

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Stilnoct® 5mg Film-Coated Tablets

(zolpidem tartrate)

Blind or partially sighted?
Is this leaflet hard to see or read?
Call +44 (0) 1302 365000
(Regulatory)

Please be ready to give the following information:
Product name: Stilnoct 5mg Film-Coated Tablets
Reference: PPA1151/030/002

Your medicine is imported from the UK under the name of 'Zolpidem Tartrate 5mg Tablets' but is marketed as 'Stilnoct 5mg Film-Coated Tablets' in Ireland.

Your medicine is available using the above name but will be referred to as Stilnoct throughout this leaflet.

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:

- What Stilnoct is and what it is used for
- What you need to know before you take Stilnoct
- How to take Stilnoct
- Possible side effects
- How to store Stilnoct
- Contents of the pack and other information

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 everyday 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 take Stilnoct

Do not take Stilnoct if:

- You are allergic (hypersensitive) to zolpidem tartrate or any of the other ingredients of this medicine (listed in section 6). 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

- Talk to your doctor or pharmacist before taking Stilnoct 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 or have ever had thoughts of harming or killing yourself
 - 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 have ever had any heart problems including slow or uneven heartbeat
 - You are elderly
 - 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

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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.

Concomitant use of Stilnoct and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe Stilnoct together with opioids the dosage and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all opioid medicines you are taking, and follow your doctor's dosage recommendation closely. It could be helpful to inform friends or relatives to be aware of sign and symptoms stated above. Contact your doctor when experiencing such symptoms.

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 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 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 together is not recommended

Stilnoct with food, drink and alcohol
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, breast-feeding and fertility
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 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 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.

Stilnoct contains lactose
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 this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Taking this medicine
- Take this medicine by mouth
 - Swallow the tablet 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 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.

Use in 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. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine 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 and 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)
- Sleep driving and other strange behaviour (sleep walking, having sex whilst asleep)
- Feeling of intense elation or confidence (euphoria)

Rare

- Decreased ability to see (visual impairment)
- Being less aware of your environment
- Problems with your liver, which will show up on blood tests
- Falling, especially in the elderly

Very Rare

- Dependence on Stilnoct in which you feel you need to take it to feel normal
- Slower breathing (respiratory depression)

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
- Depression
- Back pain

Uncommon (affects less than 1 in 100 people)

- Pains in your joints or muscles, muscle spasms
- Neck pain
- Unusual sensation or tingling of skin
- Tremor
- Change in the amount of liver enzymes – shown up in the results of blood tests
- Itching skin or skin rash
- Excessive sweating
- Weak muscles
- Feeling confused or irritable
- Feeling restless or angry
- Disturbance in attention
- Speech difficulties

Rare

- Changes in sex drive (libido)
- Hives
- Changes in the way you walk

Very Rare

- Thinking things that are not true (delusions)

Frequency Unknown

- Feeling angry or showing unusual behaviour
- Stilnoct having less effect than normal

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: medsafety@hpra.ie

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

5. How to store Stilnoct

Keep this medicine out of the sight and reach of children.
Do not store Stilnoct above 25°C. Store in the original package in order to protect from light and moisture. Do not use this medicine after the expiry date which is stated on the carton and blister strips after 'EXP'. The Expiry date refers to the last day of that month. Only use them at the time when your doctor prescribed them. If you have any leftover take them back to a pharmacist for safe disposal. Do not use this medicine if you notice discoloration, damage or any other signs of deterioration. 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 Stilnoct contains
The active substance is zolpidem tartrate. Stilnoct 5mg Film-Coated tablets contain 5mg Zolpidem tartrate. The other ingredients are: lactose monohydrate, magnesium stearate, hypromellose, microcrystalline cellulose, macrogol 400, sodium starch glycolate, titanium dioxide (E171).

What Stilnoct looks like and contents of the pack
Stilnoct tablets are round, white, film-coated tablets with no markings.

Stilnoct are available in packs of 28 tablets.

Manufacturer
Manufactured by: Sanofi Winthrop Industrie, 30-36 Avenue Gustave Eiffel, 37000 Tours, France.

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

Leaflet revision & issue date (ref): 02.11.18

PPA1151/030/002

Stilnoct® is a registered trademark of Sanofi-aventis.