

**PACKAGE LEAFLET: INFORMATION FOR THE PATIENT**

**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 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 Stilnoct is and what it is used for
2. What you need to know before you take Stilnoct
3. How to take Stilnoct
4. Possible side effects
5. How to store Stilnoct
6. 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 short-term treatment of insomnia in patients over 18 years of age 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

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE STILNOCT**

**Do not take Stilnoct :**

- As long-term treatment. Treatment should be as short as possible, because the risk of dependence increases with the duration of treatment.
- If you have ever experienced sleep walking or other behaviours which are unusual while sleeping, (such as driving, eating, making a phone call or having sex etc.) while not being fully awake after taking Stilnoct or other medicines containing zolpidem.
- If you are allergic (hypersensitive) to zolpidem tartrate or any of the other ingredients of this medicine (listed in section 6 below). Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- If your lungs do not work properly (respiratory failure)
- If you have severe liver problems
- If 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 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
- Some studies have shown an increased risk of suicidal ideation, suicide attempt and suicide in patients taking certain sedatives and hypnotics, including this medicine. However, it has not been established whether this is caused by the medicine or if there may be other reasons. If you have suicidal thoughts, contact your doctor as soon as possible for further medical advice.

- 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.
- You have ever had a mental disorder or have abused or have been dependent on alcohol or drugs.

***Use of zolpidem may lead to the development of abuse and/or physical and psychological dependence.***

The risk of dependence is greater when zolpidem is used for longer than 4 weeks. The risk of abuse and dependence is greater in patients with a history of mental disorders and/or alcohol, illicit substance or drug abuse.

***Stilnoct may cause sleep walking or other behaviours, which are unusual while sleeping,*** (such as driving, eating, making a phone call or having sex etc.) while not being fully awake. The next morning, you may not remember that you did anything during the night. If you experience any of the above, stop the treatment with Stilnoct immediately and contact your doctor or health-care provider as these sleep behaviours might put you and others at serious risk of injury.

Drinking alcohol or taking other medicines that make you drowsy together with Stilnoct might increase the risk of these sleep behaviours occurring.

***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 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 ketaconazole 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 and breast-feeding and fertility**

Use of Stilnoct is not recommended during pregnancy. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice. If used during pregnancy there is a risk that the baby is affected. Some studies have shown that there may be an increased risk of cleft lip and palate (sometimes called "harelip") in the newborn baby. Reduced fetal movement and fetal heart rate variability may occur after taking Stilnoct during the second and/or third trimester of pregnancy. If Stilnoct is taken at the end of pregnancy or during labour, your baby may show muscle weakness, a drop in body temperature, difficulty feeding and breathing problems (respiratory depression). If this medicine is taken regularly in late pregnancy, your baby may develop physical dependence and may be at risk of developing withdrawal symptoms such as agitation or shaking. In this case the newborn should be closely monitored during the postnatal period.

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

#### **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.

#### **Stilnoct contains sodium**

Stilnoct contains less than 1 mmol sodium (23mg) per tablet, that is to say essentially "sodium free"

### **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 10 mg of Stilnoct. A lower dose may be prescribed to some patients. Stilnoct 10mg tablets can be divided into equal doses (5mg each) along the score line. 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.

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, 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)
- Stilnoct may cause sleep walking or other behaviours, which are unusual while sleeping, (such as driving, eating, making a phone call or having sex etc.) while not being fully awake, see section Warnings and Precautions.

**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)

**Not known: frequency cannot be estimated from the available data**

- Delirium (a sudden and severe change in mental state that causes a person to appear confused or disoriented)

**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)

**Not known: frequency cannot be estimated from the available data** • 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.

Website: [www.hpra.ie](http://www.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 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 use this medicine after the expiry date which is stated on the carton. 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 left over take them back to a pharmacist.

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 5 mg Film-Coated Tablets contain 5 mg zolpidem tartrate.

Stilnoct 10 mg Film-Coated tablets contain 10 mg zolpidem tartrate.

The other ingredients are: 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, film-coated 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 14 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 - Fax: 01 403 5687

Email: [IEmedinfo@sanofi.com](mailto:IEmedinfo@sanofi.com)

#### **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.

#### **This leaflet was last revised in December 2021.**

Stilnoct is a registered trademark.