INFORMATION FOR PATIENTS

Stilnoct® 10mg Film-Coated Tablets (zolpidem tartrate)

Your medicine is imported from the UK under the name of 'Zolpidem Tartrate 10mg Tablets' but is marketed as 'Stilnoct 10mg Film-Coated Tablets' in Ireland.

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 get serious, or if you notice any side effect 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. 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 that are causing you severe distress or that are affecting your 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. Before you take 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 have a problem where you stop breathing for short periods at night (sleep apnoea)
- You have a problem that causes severe muscle weakness (myaesthenia gravis)
- You have been told by your doctor that you have a mental illness (psychosis)
- 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.

Take special care with Stilnoct

Check with your doctor or pharmacist before taking this 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

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

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:
- Medicines for some mental health problems (antipsychotics)
- Medicines for depression such as sertraline
- Medicines for epilepsy (anti-convulsants)
- Medicines used in surgery (anaesthetics)
- Medicines to calm or reduce anxiety or for sleep problems
- Medicines for hay fever, rashes or other allergies that can make you sleepy (sedative antihistamines)
- Some medicines for moderate to severe pain (narcotic analgesics) such as codeine, methadone, morphine, oxycodone, pethidine or tramadol

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

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 advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

On the day after taking Stilnoct, do not drive or use machinery or tools if you feel sleepy, dizzy or confused. 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
- Take just before bedtime. Make sure you have at least 8 hours for sleep after taking this medicine
- 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
- Relaxated 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, swelling 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
- Failing, 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 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

Uncommon (affects less than 1 in 100 people)
- Feeling confused or irritable

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
- Stilnoct having less effect than normal

Talk to your doctor or pharmacist if any of the side effects gets serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet.

5. How to store Stilnoct
Keep Stilnoct out of the sight and reach of children.
There are no special storage conditions for Stilnoct 10mg Film-Coated Tablets.

Do not take this medicine after the month shown on the blister and carton pack.
Only use them at the time when your doctor prescribed them. If you have any left over take them back to a pharmacist for safe disposal.
If your tablets appear to be discoloured, damaged or show any other signs of deterioration, please return them to your pharmacist who will advise you.
Medicines should not be disposed 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 10mg Film-Coated Tablets contain 10mg zolpidem tartrate.
The film-coated tablets also contain lactose monohydrate, magnesium stearate, hypromellose, microcrystalline cellulose, macrogol 400, sodium starch glycollate and titanium dioxide (E171).

What Stilnoct looks like and contents of the pack
Stilnoct 10mg Film-Coated Tablets are oblong, white, scored tablets engraved ‘SN10’ on one side and plain on the other.
Stilnoct 10mg Film-Coated Tablets are available in packs of 28 tablets.

Manufacturer
Stilnoct 10mg Film-Coated Tablets are manufactured by: Sanofi Winthrop Industrie, 6, Boulevard De L’Europe, 21800 Quetigny, France.

Procured from within the EU by the PPA holder: Imbat Ltd, Unit L2, North Ring Business Park, Santry, Dublin 9.

The product is repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK. Distributed by: Eurodrug Ltd, Santry, Dublin 9.

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