PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

STILNOX MR, 12,5 mg, modified release tablets

Zolpidem tartrate

Contains sugar (138,913 mg lactose monohydrate per tablet).

Read all of this leaflet carefully before you start taking STILNOX MR 12,5

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor, pharmacist, nurse or other health care provider.
- STILNOX MR 12,5 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What STILNOX MR 12,5 is and what it is used for
2. What you need to know before you take STILNOX MR 12,5
3. How to take STILNOX MR 12,5
4. Possible side effects
5. How to store STILNOX MR 12,5
6. Contents of the pack and other information

1. What STILNOX MR 12,5 is and what it is used for

STILNOX MR 12,5 contains a medicine called zolpidem tartrate and belongs to a group of medicines called hypnotics. It works by acting on your brain to help you sleep.

STILNOX MR 12,5 is used to initiate sleep in adults below the age of 65 years with sleeping difficulties, also called insomnia, for a short-term only.

2. What you need to know before you take STILNOX MR 12,5

Do not take STILNOX MR 12,5:

- if you are hypersensitive (allergic) to zolpidem tartrate or any of the other ingredients of STILNOX MR 12,5 (listed in section 6). Signs of an allergic reaction include; rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.
- if you have myasthenia gravis (a condition in which the muscles become weak and tire easily).
- if you have sleep apnoea (a condition where you temporarily stop breathing while you sleep).
- if you have severe lung problems.
- if you have serious liver problems.
- if you are a child under 18 years of age or an adult over the age of 65 years.
- if you are pregnant, intend to become pregnant or are breastfeeding.

Warnings and precautions

Take special care with STILNOX MR 12,5:

- The use of STILNOX MR 12,5 may lead to the development of abuse and/or physical and mental dependence. The risk of abuse and dependence is greater in patients with a history of mental disorders and/or alcohol, illegal substance, or medicine abuse. Tell your health care provider if you have ever had a mental disorder or have abused or have been addicted to alcohol or other medicines.
- Please consult with your doctor if you notice that you cannot or do not want to stop taking STILNOX MR 12,5 or if you feel that you need to take STILNOX MR 12,5 more often than prescribed by your doctor.
- Use with caution if you have mild to moderate breathing or chest problems.
- If your sleep problems persist or worsen after a short period of treatment, consult your doctor.

- If your sleep problems return while you are taking STILNOX MR 12,5, consult your doctor. When medicines for sleep such as STILNOX MR 12,5 are used for more than a few weeks, they may lose their effectiveness to help you sleep. This is known as “tolerance”.
- You may have temporary memory loss (amnesia) when taking STILNOX MR 12,5. This can usually be avoided if you get a full night’s of sleep (7 to 8 hours) before being active again.
- Some people taking STILNOX MR 12,5 may have changes in behaviour and thinking (see section 4). If you or your family notice any changes in your behaviour, or if you have any unusual or disturbing thoughts, consult your doctor immediately.
- If you have a history or are experiencing the following symptoms while taking STILNOX MR 12,5: sleep walking, sleep driving, preparing and eating food, making phone calls or having sex, with no memory of these events. Consult your health care provider immediately if you experience any of the above symptoms.
- Use with caution if you have mild to moderate liver problems.
- If you suffer from mental disorders (depression or schizophrenia) or epilepsy (fits).
- If you may be at risk of getting into a regular pattern or habit of taking STILNOX MR 12,5.

Children and adolescents

Do not give STILNOX MR 12,5 to children or adolescents under 18 years of age.

Other medicines and STILNOX MR 12,5

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines).

You should specifically tell you doctor if you take:

- Other medicines that act on the brain such as:
    - medicines used in the treatment of mental conditions (antipsychotics, hypnotics, anxiolytics/sedatives, antidepressants)
    - medicines used for strong pain relief (narcotic analgesics)

- medicines used for the treatment of seizures/convulsions (antiepileptic medicines)
- anaesthetics
- medicines used in the treatment of allergies (antihistamines that cause sleepiness)

The combination of these medicines with STILNOX MR 12,5 may make you drowsier than it should and may increase the next-day psychomotor impairment effects, including impaired driving ability. In addition, you may be euphoric (increase of well-being) if narcotic analgesics (morphine and opiates) are combined with STINOX MR 12,5.

- Rifampicin (used to treat infections) as it may decrease the effect of STILNOX MR 12,5 on sleep.
- Ketoconazole (used to treat infections) increases the effect of STILNOX MR 12,5.
- Fluvoxamine (an antidepressant medicine) as it may increase the effect of STILNOX MR 12,5. It is not recommended to take STILNOX MR 12,5 with fluvoxamine.
- Ciprofloxacin (antibiotic used to treat infections) as it may increase the effect of STILNOX MR 12,5. It is not recommended to take STILNOX MR 12,5 with ciprofloxacin.
- St John's Wort (a herbal medicine used for mood swings and depression). It is not recommended to take STILNOX MR 12,5 with St John's Wort.
- Opioids (medicines used for pain relief, also contained in some cough medicines). Concomitant use of STILNOX MR 12,5 and opioids increases the risk of drowsiness, difficulties in breathing, coma and may be life-threatening. Because of this, the concomitant use with STILNOX MR 12,5 should only be considered when other treatment options are not possible. Please tell your doctor about all opioid medicines you are taking.

STILNOX MR 12,5 with food, drink and alcohol

You should not drink alcohol while you are taking STILNOX MR 12,5.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, you should not take STILNOX MR 12,5 (see Do not take STILNOX MR 12,5).

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking STILNOX MR 12,5.

Driving and using machines

STILNOX MR 12,5 may makes you sleepy, therefore caution should be exercised when operating machinery or driving motor vehicles.

STILNOX MR 12,5 has a major influence on the ability to drive and use machines. On the day after taking STILNOX MR 12,5, 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 STILNOX MR 12,5 and driving, using machinery and working at heights to minimise the above listed effects.

Do not drink alcohol or take other psychoactive medicines while you are taking STILNOX MR 12,5 as it can increase the above listed effects.

STILNOX MR 12,5 contains lactose monohydrate

STILNOX MR 12,5 contains lactose monohydrate, 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 STILNOX MR 12,5.

3. How to take STILNOX MR 12,5

Do not share medicines prescribed for you with any other person.

Always take STILNOX MR 12,5 exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual adult (< 65 years) dose of STILNOX MR 12,5 is one tablet (12,5 mg) at night, immediately before bedtime or in bed. The dose of one tablet (12,5 mg) at night should not be exceeded.

Swallow the tablet whole with a full glass of water.

STILNOX MR 12,5 should be taken in a single intake and not taken again during the same night.

STILNOX MR 12,5 should only be used for a few days to 2 weeks with a maximum, including the tapering off (gradual reduction of your dose before stopping treatment over a period) process, of 4 weeks.

DO NOT TAKE MORE THAN THE DOSAGE RECOMMENDED BY YOUR DOCTOR.

If you have the impression that the effect of STILNOX MR 12,5 is too strong or too weak, tell your doctor or pharmacist.

If you take more STILNOX MR 12,5 than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre and tell them how many tablets have been taken. If you take too much STILNOX MR 12,5, your consciousness may be impaired, ranging from drowsiness to light coma.

If you forget to take STILNOX MR 12,5

STILNOX MR 12,5 must only be taken at bedtime. If you forget to take the tablet before you go to bed, and you wake up late in the night or very early in the morning, do not take it. If you are not sure what to do, ask your doctor.

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

If you stop taking STILNOX MR 12,5

Keep taking STILNOX MR 12,5 until your doctor tells you to stop. Do not stop taking STILNOX

MR 12,5 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 STILNOX MR 12,5 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 experience 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

STILNOX MR 12,5 can have side effects.

Not all side effects reported for STILNOX MR 12,5 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking STILNOX MR 12,5, please consult your health care provider for advice.

If any of the following happens, stop taking STILNOX MR 12,5 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to STILNOX MR 12,5. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- 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. These may be signs of a problem with your liver.
- slower breathing or breathing difficulties (respiratory depression)
- STILNOX MR 12,5 may cause sleep walking or other unusual behaviour (such as driving, eating, making a phone call or having sex etc.) while not being fully awake, some of which have been associated with serious injuries and death. Alcohol and some medicines for depression or anxiety can increase the chance that this serious effect will happen.
- changes in the way your heart beats, for example, if you notice it beating faster.
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.
- pain or difficulty in passing urine.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- influenza
- anxiety
- disorientation

- drowsiness
- dizziness
- diarrhoea
- nausea
- constipation
- abdominal pain
- headache
- increased sleep problems
- hallucinations
- agitation
- nightmares
- memory difficulties
- tiredness
- visual disturbances
- neck and back pain, muscle cramp

Less frequent side effects:

- confusion
- irritability
- balance disorder
- blurred vision
- otitis externa (outer ear infection)
- respiratory tract infection (lower and upper)
- appetite disorder
- vomiting
- gastroenteritis (nausea, vomiting, stomach cramps)
- decreased concentration
- restlessness

- aggressiveness
- delusion
- rage
- abnormal behaviour
- libido disorders (changes in sex drive)
- unsteadiness, fall (mainly in older patients and when STILNOX MR 12,5 is not taken in accordance with the prescribing recommendations)
- vertigo (sensation of spinning or swaying), ringing in the ears
- cough, dry and irritated throat
- muscle weakness, joint pain
- painful, heavy menstrual periods, vaginal dryness
- tolerance (loss of effectiveness of the sleep medicine)
- dependence (need to continue the sleep medicine associated with unpleasant symptoms when the sleep medicine is suddenly stopped)
- unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)
- speech problems
- abnormal physical weakness or lack of energy
- fever

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of STILNOX MR 12,5.

You can report any side effects directly to Sanofi’s Pharmacovigilance Unit at

za.drugsafety@sanofi.com (email) or 011 256 3700 (tel).

5. How to store STILNOX MR 12,5

Store all medicines out of reach of children.

Store at or below 30 °C.

Protect from light and moisture.

Tablets must be kept in blisters in the carton at all times until required for use.

Do not take STILNOX MR 12,5 after the expiry date shown on the carton and blister.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

6. Contents of the pack and other information

What STILNOX MR 12,5 contains

The active substance is zolpidem tartrate.

Each STILNOX MR 12,5 tablet contains 12,5 mg zolpidem tartrate.

The other ingredients are colloidal anhydrous silica (200), hypromellose (6 mPa.s, 4000 mPa.s), iron oxide yellow (E172), lactose monohydrate, magnesium stearate, microcrystalline cellulose (Avicel PH101), opadry II 32F20797X (hypromellose (15 mPa.s), indigotine (E132) aluminium lake, macrogol 3350, titanium dioxide (E171)), potassium hydrogen tartrate, sodium starch glycolate (type A).

What STILNOX MR 12,5 looks like and contents of the pack

Blue, round, biconvex tablet engraved ZMR on one face.

Clear, colourless, transparent, rigid PVC/Aluminium foil blister containing 7, 14 , 28 or 100 tablets in a carton.

Holder of certificate of registration

sanofi-aventis south africa (pty) ltd

Hertford Office Park, Building I, 5th Floor

90 Bekker Road, Vorna Valley

Midrand 2196

South Africa

011 256 3700

This leaflet was last revised in

Date of registration: 10 October 2008

Date of update: 15 June 2023

Registration number

A40/2.2/0441