

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

STILNOX MR 12.5 (modified release tablets)

Zolpidem tartrate 12,5 mg 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 or your pharmacist.
- 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.

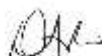
WHAT STILNOX MR 12.5 CONTAINS:

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, hypromellose, iron oxide yellow (E172), lactose monohydrate, magnesium stearate, microcrystalline cellulose, opadry II 32F20797X (hypromellose, indigotine (E132) aluminium lake, macrogol 3350, titanium dioxide), potassium hydrogen tartrate, sodium starch glycolate.

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

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WHAT STILNOX MR 12.5 IS USED FOR:

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.


BEFORE YOU TAKE STILNOX MR 12.5:

Do not take STILNOX MR 12.5:

- if you are hypersensitive (allergic) to zolpidem or any of the other ingredients of STILNOX MR 12.5 (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.

Take special care with STILNOX MR 12.5:

- If you have ever been addicted to drugs or alcohol, talk to your doctor or pharmacist. You should not take STILNOX if you have a history of drug or alcohol abuse.
- Use with caution if you have mild to moderate breathing or chest problems.

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- 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 medications 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 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 POSSIBLE SIDE EFFECTS). If you or your family notice any changes in your behaviour, or if you have any unusual or disturbing thoughts, consult your doctor immediately.
- Use with caution if you have mild to moderate liver problems.
- If you suffer from depression, epilepsy or schizophrenia.
- If you may be at risk of getting into a regular pattern or habit of taking STILNOX MR 12.5.


Pregnancy and Breastfeeding

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 your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery:

STILNOX MR 12.5 may make you sleepy, therefore caution should be exercised when operating machinery or driving motor vehicles.

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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 substances while you are taking STILNOX MR 12.5 as it can increase the above listed effects.

Important information about some of the ingredients of STILNOX MR 12.5:


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.

Patients with the rare hereditary conditions of lactose or galactose intolerance should not take STILNOX MR 12.5.

Taking other medicines with STILNOX MR 12.5:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

You should not drink alcohol while you are taking STILNOX MR 12.5.

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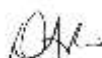
You should specifically tell you doctor if you take:

- 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 (sedative antihistamines)

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 STILNOX MR 12.5.

- Medicines that decrease the normal elimination of zolpidem by the liver.
- 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.

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- 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.

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 instructed you. You should check with your doctor or pharmacist if you are unsure.


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.

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 for with a maximum, including the tapering off process, of 4 weeks.

Swallow the tablets whole with a full glass of water.

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

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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 overdose, 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.

Dependence and abuse:


The use of STILNOX MR 12.5 may lead to you becoming dependent on taking STILNOX MR 12.5. 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 to you by your doctor.

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.

Effects when treatment with STILNOX MR 12.5 is stopped:

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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 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.

POSSIBLE SIDE EFFECTS:

STILNOX MR 12.5 can have side effects.

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Stop taking STILNOX MR 12.5 and tell your doctor immediately or go to the nearest hospital straight away if any of the following happen:


- swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or hives (an itchy, lumpy rash)
- fainting
- 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. This may be signs of a problem with your liver.
- slower breathing or breathing difficulties (respiratory depression)

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 or pharmacist if any of the following side effects get serious or last longer than a few days.

Frequent side effects:


- influenza
- anxiety
- disorientation
- drowsiness
- dizziness
- diarrhoea

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- 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
- respiratory tract infection (lower and upper)
- appetite disorder
- vomiting
- gastroenteritis

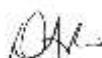
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- decreased concentration
- restlessness
- aggressiveness
- delusion
- rage
- abnormal behavior
- sleep walking (see “sleep-driving and other sleep-related behaviour”)
- libido disorders (changes in sex drive)
- unsteadiness, fall (mainly in older patients and when STILNOX MR 12.5 is not taken in accordance with the prescribing recommendations)
- muscle weakness
- 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

Sleep-driving and other sleep-related behaviour:

There have been reports of people doing things while asleep that they do not remember when waking up after taking STILNOX MR 12.5. This includes sleep-driving, sleepwalking, preparing and eating food, and having sex. Alcohol and some medicines for depression or anxiety can increase the chance that this serious effect will happen.

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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 doctor, pharmacist or other healthcare professional for advice.

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

STORAGE AND DISPOSING OF STILNOX MR 12.5:

Store all medicines out of reach of children.

It should be stored below 30 °C protected from light and moisture.

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

Do not take this medicine 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.

PRESENTATION OF STILNOX MR 12.5:

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

IDENTIFICATION:

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

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REGISTRATION NUMBER:

A40/2.2/0441

NAME AND ADDRESS OF REGISTRATION HOLDER:

sanofi-aventis south africa (pty) ltd

2 Bond Street


Midrand, 1685

South Africa

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