STILNOX CR®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I taking STILNOX CR?

STILNOX CR contains the active ingredient zolpidem tartrate. STILNOX CR is used to initiate and maintain sleep in those with sleeping difficulties, also called insomnia in patients over 18 years of age. For more information, see Section 1. Why am I taking STILNOX CR? in the full CMI.

2. What should I know before I take STILNOX CR?

Do not use if you have ever had an allergic reaction to STILNOX CR or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, have been drinking alcohol, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section 2. What should I know before I take STILNOX CR? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with STILNOX CR and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take STILNOX CR?

- In Adults: Usual dose is one 12.5 mg tablet taken just before bedtime.
- In people over 65 years of age: The dose is one 6.25 mg tablet taken just before bedtime.

More instructions can be found in Section 4. How do I take STILNOX CR? in the full CMI.

5. What should I know while taking STILNOX CR?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using STILNOX CR. • If you become pregnant or suspect that you are pregnant while you are taking this medicine, stop taking it and tell your doctor or pharmacist immediately.
Things you should not do	• Do not take STILNOX CR if you have sleep apnoea, myasthenia gravis, severe liver problems, acute and / or severe lung problems or if you have previously experienced complex sleep behaviours such as sleep walking. • Do not give STILNOX CR to a child or adolescent
Driving or using machines	• You should not operate dangerous machinery or drive motor vehicles for 8 hours after you take it. You should also be careful the next morning when you wake up.
Drinking alcohol	• You should not drink alcohol while you are taking STILNOX CR.
Looking after your medicine	• Keep the medicine in a cool, dry place where the temperature stays below 30°C.

For more information, see Section 5. What should I know while using STILNOX CR? in the full CMI.

6. Are there any side effects?

Common side effects are: drowsiness, sleepiness, dizziness, headache, fatigue, anxiety, disorientation, slowness in thinking and movement, poor attention and concentration, loss of memory, diarrhoea, nausea, constipation, muscle cramps or aching, muscle tenderness or weakness not caused by exercise, neck and back pain, influenza or flu-like symptoms and visual disturbances.

If any of the following happen, stop taking this medicine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital: swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing, hives, fainting.

Sleep walking, driving motor vehicles and other unusual, and on some occasions dangerous, behaviours whilst apparently asleep may also occur. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

WARNING: ZOLPIDEM MAY BE ASSOCIATED WITH UNUSUAL AND POTENTIALLY DANGEROUS BEHAVIOURS WHILST APPARENTLY ASLEEP. THESE HAVE INCLUDED SLEEP WALKING, DRIVING MOTOR VEHICLES AND OTHER BIZARRE BEHAVIOURS. SOME MEDICINES MAY INTERACT WITH ZOLPIDEM AND PARTICULAR CAUTION IS NEEDED WITH OTHER DRUGS THAT MAY ALSO ACT ON THE BRAIN; BEFORE YOU TAKE ZOLPIDEM REFER TO THE "TAKING OTHER MEDICINES" SECTION BELOW OR ASK YOUR DOCTOR OR PHARMACIST. YOU MUST NOT DRINK ALCOHOL WHEN YOU TAKE ZOLPIDEM. DO NOT TAKE ZOLPIDEM FOR MORE THAN 4 WEEKS. IF YOUR SLEEP PROBLEMS CONTINUE, CONSULT YOUR DOCTOR.

STILNOX CR®

Active ingredient: *zolpidem tartrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using STILNOX CR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about STILNOX CR.**

Where to find information in this leaflet:

1. Why am I taking STILNOX CR?
2. What should I know before I take STILNOX CR?
3. What if I am taking other medicines?
4. How do I take STILNOX CR?
5. What should I know while taking STILNOX CR?
6. Are there any side effects?
7. Product details

1. Why am I taking STILNOX CR?

STILNOX CR contains the active ingredient zolpidem tartrate. STILNOX CR is used to initiate and maintain sleep in those with sleeping difficulties, also called insomnia in patients over 18 years of age. It is not recommended for use for more than 4 weeks at a time.

STILNOX CR has a different chemical structure to other sleeping tablets. STILNOX CR works by binding to special sites in the brain which produce sleep.**Your doctor, however, may prescribe STILNOX CR for another purpose.**

2. What should I know before I take STILNOX CR?

Warnings

Do not take STILNOX CR if:

- you are allergic to zolpidem tartrate, or any of the ingredients listed at the end of this leaflet.

  Always check the ingredients to make sure you can use this medicine.
- you have been drinking alcohol or you believe that you may have alcohol in your bloodstream.
- you have sleep apnoea (a condition where you temporarily stop breathing while you sleep).
- you have myasthenia gravis (a condition in which the muscles become weak and tire easily).
- you have severe liver problems
- you have acute and/or severe lung problems
- you have previously experienced complex sleep behaviours after taking this medicine including sleepwalking, sleep-driving, and/or engaging in other activities while not fully awake.

Do not give STILNOX CR to a child or adolescent under 18 years of age.

There is no experience with its use in children or adolescents under 18 years of age.

Check with your doctor if you:

- have any problems with your breathing or if you often snore while you are asleep.
- have ever been addicted to alcohol or any drug or medicine or if you have ever suffered from a mental illness. If you have, you may be at risk of getting into a regular pattern or habit of taking STILNOX CR.
- have or have had any other medical conditions especially the following: problems with your heart, liver, kidneys or lungs, epilepsy, depression, mental illness, for example, schizophrenia.
- plan to have surgery.
- have allergies to any of the ingredients listed at the end of this leaflet
- take any medicines for any other condition.

Talk to your doctor or pharmacist if you have ever had a mental disorder or have abused or have been dependent on alcohol or drugs.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant, suspect that you are pregnant, or intend to become pregnant.

Like most medicines of this kind, STILNOX CR is not recommended to be used during pregnancy. Your doctor will discuss the risks and benefits of taking it if you are pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

STILNOX CR can pass into breast milk. Your doctor will discuss the risks and benefits of using it if you are breast-feeding or planning to breast-feed.

Do not take it after the expiry date (EXP) printed on the pack.

Do not take it if the packaging is damaged or shows signs of tampering.

Contains sugars (as lactose).

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with STILNOX CR and affect how it works.

Medicines that may <u>increase</u> the effect of STILNOX CR include:

- alcohol
- medicines to treat depression, anxiety and mental illness
- medicine used to produce calmness or to help you sleep
- medicines to treat epilepsy
- pain relievers
- muscle relaxants
- antihistamines
- ciprofloxacin a medicine used to treat infections
- ketoconazole, a medicine to treat antifungal infections
- opioids

These medicines may increase drowsiness. This may affect your ability to drive a car or operate dangerous machinery. You may need to use different amounts of your medicine, or take different medicines. Your doctor will advise you.

Medicines that may <u>reduce</u> the effect of STILNNOX CR include:

- St John's Wort (also known as Hypericum), a herbal remedy used to treat depression
- rifampicin a medicine used to treat infection

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect STILNOX CR.

4. How do I take STILNOX CR?

How much to take

- The usual adult dose of STILNOX CR is one 12.5 mg tablet taken just before you go to bed.
- If you are over 65 years of age the dose is one STILNOX CR 6.25 mg tablet taken just before you go to bed.
- If you have a liver problem, the usual recommended dose is one STILNOX CR 6.25 mg tablet.

  Do not take STILNOX CR if you have a severe liver problem.
- Your doctor may have prescribed a different dose. Follow the instructions provided and use STILNOX CR until your doctor tells you to stop.
- If you take the wrong dose, STILNOX CR may not work as well.
- If you take too much your consciousness may be impaired (see 'If you take too much STILNOX CR' below).
- Ask your doctor if you are unsure of the correct dose for you. They will tell you exactly how much to take.

When to take STILNOX CR

- Take STILNOX CR immediately before you go to bed or while you are in bed
- STILNOX CR should only be taken when you are able to get a full night's sleep (7 to 8 hours) before you need to be active again. It should be taken in one dose and not be re-administered during the same night.

How long to take it

- Usually, STILNOX CR or any other medicines to treat sleeping disorders should only be used for short periods (e.g. 2 to 4 weeks). Continuous long term use is not recommended unless advised by your doctor.

Ask your doctor or pharmacist if you are not sure how long to take the medicine for.

How to take STILNOX CR

- **Swallow the tablet whole with a full glass of water**
- **Do not crush or chew the tablet**: Each STILNOX CR tablet has been especially designed to release the right dose of medicine while you sleep. If you crush, chew or divide STILNOX CR tablets they will not work properly.
- If you take STILNOX CR on an empty stomach it may work more quickly

If you forget to take STILNOX CR

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. You may have trouble waking at your normal time.

If you are not sure what to do, ask your doctor.

If you take too much STILNOX CR

If you think that you have used too much STILNOX CR, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much your consciousness may be impaired ranging from drowsiness to light coma.

5. What should I know while taking STILNOX CR?

Things you should do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking STILNOX CR.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking STILNOX CR.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

If you become pregnant or suspect that you are pregnant while you are taking this medicine, stop taking it and tell your doctor or pharmacist immediately.

Call your doctor straight away if you:

- have any of the serious side effects listed in section 6

Remind any doctor, dentist or pharmacist you visit that you are taking STILNOX CR.

Things you must not do

- Do not take more than the recommended dose unless your doctor tells you to. This can increase the risk of side effects.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not drink alcohol before or after taking this medicine. This can increase the risk of side effects or the effects of alcohol could be made worse while taking STILNOX CR.

Things to be careful of:

- If you are over 65 and unwell or taking other medicines. You may be more sensitive to some of the side effects of STILNOX CR. Some patients may be particularly susceptible to the sedative effects of the medication, which may increase the possibility of a fall.
- STILNOX CR can cause drowsiness and a decreased level of consciousness. Keep STILNOX CR in a safe place to protect it from theft as it may be used illicitly for criminal action (which could be dangerous) particularly in combination with alcohol, when given without knowledge of the victim. Never give your STILNOX CR to anyone else because it may harm them.

After taking STILNOX CR

- Sleep medicines should in most cases, be used only for short periods of time. If your sleep problems continue, consult your doctor.
- Some medicines can cause dependence, especially when they are used regularly for longer than a few weeks. People who have been dependent on alcohol or other drugs in the past may have a higher chance of becoming addicted to sleep medicines. If you have been addicted to alcohol or drugs in the past, it is important to tell your doctor before starting STILNOX CR.
- Sometimes when medicines are stopped suddenly, after being used for a long time, withdrawal symptoms may occur. Symptoms of withdrawal may include abdominal and muscle cramps, vomiting and sweating. In some cases your insomnia may appear worse for a short time which may be accompanied with other reactions including mood changes, anxiety and restlessness; speak to your doctor if this occurs. Patients taking part in trials have not had any problems when they stopped taking STILNOX CR. However, let your doctor know if you have any problems when you stop taking STILNOX CR.

Driving or using machines

Because STILNOX CR will make you sleepy, you should not operate dangerous machinery or drive motor vehicles for 8 hours after you take it. You should also be careful the next morning when you wake up.

Make sure you know how you react to STILNOX CR before you drive a car or operate machinery. This is very important if you are taking other drugs that also make you drowsy.

Drinking alcohol

You should not drink alcohol while you are taking STILNOX CR.

Tell your doctor if you drink alcohol.

Alcohol may increase the risk of side effects or the effects of alcohol could be made worse while taking STILNOX CR.

Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the box or the blister pack they may not keep well.
- Keep the medicine in a cool, dry place where the temperature stays below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Tell your doctor as soon as possible if you do not feel well while you are taking STILNOX CR.

Less serious side effects

Less serious side effects	What to do
Head and neurology related: • drowsiness • dizziness • headache • fatigue • anxiety • disorientation • hallucinations • nightmares • slowness in thinking and movement • poor attention and concentration • memory impairment and loss • unexpected changes in behaviour. These have included rage reactions, worsened insomnia, confusion, agitation, hallucinations, delirium, and other forms of unwanted behaviour. **Gastrointestinal related:** • stomach discomfort, indigestion, wind, frequent bowel movements • diarrhoea, nausea and vomiting • constipation • changes in appetite **Musculoskeletal related** • aching muscle, muscle weakness or tenderness not caused by exercise • muscle cramps • neck and back pain **Infection related:** • influenza or flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills **Eye related:** • visual disturbances Although these side effects can occur at the usual recommended doses, the risk of these behaviours occurring may also be increased if you take more than the recommended dose.	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Allergic reactions: • swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing • hives • fainting **Sleepwalking and associated behaviours:** • sleep walking, driving motor vehicles and other unusual, and on some occasions dangerous, behaviours whilst apparently asleep. These have also included preparing and eating food, making phone calls or having sexual intercourse. People experiencing these effects have had no memory of the events.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Alcohol can increase the risk of sleep walking and other related behaviours. These side effects can also occur without the presence of alcohol. Although these side effects can occur at the usual recommended doses, the risk of these behaviours occurring may also be increased if you take more than the recommended dose.

Some sleep medicines may cause a short-term memory loss. When this occurs, a person may not remember what has happened for several hours after taking the medicine. This is usually not a problem since most people fall asleep after taking the medicine.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What STILNOX CR contains

Active ingredient **(main ingredient)**	Each STILNOX CR 6.25 mg tablet contains zolpidem tartrate 6.25 mg as the active ingredient. Each STILNOX CR 12.5 mg tablet contains zolpidem tartrate 12.5 mg as the active ingredient.
Other ingredients **(inactive ingredients)**	colloidal anhydrous silica hypromellose indigo carmine iron oxide yellow (STILNOX CR 12.5 mg) iron oxide red (STILNOX CR 6.25 mg) macrogol 3350 magnesium stearate microcrystalline cellulose potassium hydrogen tartrate sodium starch glycollate type A titanium dioxide
Potential allergens	lactose monohydrate

STILNOX CR does not contain gluten.

What STILNOX CR looks like

STILNOX CR 6.25 mg tablets are pink, bi-convex two-layer tablets engraved with ZMR on one side (Aust R 120707).

STILNOX CR 6.25 mg tablets are available in boxes of 14 tablets.

STILNOX CR 12.5 mg tablets are blue, bi-convex two-layer tablets engraved with ZMR on one side (Aust R 120713).

STILNOX CR 12.5 mg tablets are available in boxes of 14 tablets.

Who distributes STILNOX CR

Distributed by:

sanofi-aventis australia pty ltd

International Tower 3, Level 23

300 Barangaroo Avenue

Sydney NSW 2000

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

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