

SWICLONE®

ZOPICLONE 7.5 mg Tablet

The active ingredient of **SWICLONE®** Tablet is Zopiclone 7.5 mg. Each tablet contains 7.5 mg of Zopiclone Ph. Eur.

The other components are:

Lactose monohydrate, calcium hydrogen phosphate dehydrate, corn starch, carmellose sodium, magnesium stearate, OPADRY 02A38602, titanium dioxide (E171), hypromellose.

SWICLONE® is a prescription medication that is intended to help you sleep if you have transient and short term insomnia which are expressed as difficulty in falling asleep, often waking during the night, early awakening in the morning or the combination of the 3 symptoms.

CLINICAL PHARMACOLOGY

SWICLONE® (zopiclone 7.5 mg), a cyclopyrrolone derivative, is a short-acting hypnotic agent. **SWICLONE®** Tablet is structurally unrelated to existing hypnotics. However, the pharmacological profile of **SWICLONE®** Tablet is similar to that of the benzodiazepines. **SWICLONE®** Tablet pharmacological properties are: hypnotic, sedative, anxiolytic, anti-convulsant, muscle-relaxant. These effects are related to a specific agonist action at central receptors belonging to the GABA_A macromolecular complex, modulating the opening of the chloride ion channel.

INDICATION AND USES

Zopiclone, the active substance in **SWICLONE®** Tablets is used to treat sleep problems such as:

- Difficulty falling asleep
- Waking in the middle of the night
- Waking too early
- Severe or upsetting sleep problems that are caused by your mood or mental health problems.

SWICLONE® Tablet can be used for both temporary and longer lasting sleep problems. However, **SWICLONE®** Tablet is not meant to be used every day for long periods of time or to treat depression. Ask your doctor for advice if you are unsure

CONTRAINDICATIONS

- Hypersensitivity to the active substance or any of the ingredients in the product,
- Severe respiratory insufficiency,
- Sleep apnoea syndrome,
- Severe, acute or chronic hepatic insufficiency (risk of encephalopathy),
- Myasthenia gravis
- Due to the lactose content, this medicinal product is contraindicated in the event of congenital galactosaemia, glucose or galactose malabsorption syndrome or lactase deficiency.

INTERACTIONS

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

This include medicines you buy without a prescription, including herbal medicines.

This is because **SWICLONE®** Tablet can affect the way some other medicines work. Also some medicines can affect the way **SWICLONE®** Tablet works. Tell your doctor if you are taking any of the following medicines.

The following medicines may increase the effect of **SWICLONE®** Tablet:

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

The following medicines can increase the chance of you getting side effects when taken with **SWICLONE®** Tablets. To make this less likely, your doctor may decide to lower your dose of **SWICLONE®** Tablet

- Some antibiotics such as clarithromycin or erythromycin
- Some medicines for fungal infections such as ketoconazole and itraconazole
- Ritonavir a protease inhibitor. The following medicines may reduce the effect of **SWICLONE®** Tablet:
- Some medicines for epilepsy such as carbamazepine, phenobarbital and phenytoin
- Rifampicin (an antibiotic) – for infections
- Products containing St. John's wort (herb used for depression and mood swings).

SWICLONE® Tablets with food and drink

Do not drink alcohol while you are taking **SWICLONE®** Tablet. Alcohol can increase the effects of **SWICLONE®** Tablet and make you sleep very deeply so that you do not breathe properly or have difficulty waking.

WARNINGS

The cause of insomnia should be identified wherever possible. The underlying factors should be treated before a hypnotic is prescribed. The failure of insomnia to remit after a 7-14 day course of treatment may indicate the presence of a primary psychiatric or physical disorder, which should be evaluated.

Complex Sleep-related Behaviours:

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 and sleep walking. Alcohol and some medicines for depression or anxiety can increase the chance that this serious effect will happen. The activities you may do in these situations can put you and people around you in danger. Reported activities included driving a car (sleep-driving), leaving the house, making and eating food, talking on the phone etc.

- a. Do not take more **SWICLONE®** Tablet than prescribed
- b. Do not take **SWICLONE®** Tablet if you drink alcohol
- c. Talk to your doctor about all of your medicines, including over-the-counter medicines and herbal products. Your doctor will tell you if you can take **SWICLONE®** Tablet with your other medicines
- d. You and the people close to you should watch for the type of unusual behaviour described above. If you find out that you have done any of such activities for which you have no memory, you should inform your doctor.

PRECAUTION

Pregnancy, Breast-feeding and Fertility:

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant, or think you may be pregnant. Do not take **SWICLONE®** Tablets during the last 3 months of pregnancy or during labour because it may be harmful to your baby.

Do not breast-feed if you are taking **SWICLONE®** Tablets. This is because small amounts may pass into mother's milk. If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking any medicine. Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

Like other medicines used for sleep problems, **SWICLONE®** Tablet can cause slowing of your normal brain function (central nervous system depression).

The risk of psychomotor impairment including driving ability is increased if:

- You take **SWICLONE®** Tablet within 12 hours of performing activities that require mental alertness
- You take higher than the recommended dose of **SWICLONE®** Tablet
- You take **SWICLONE®** Tablet while already taking another central nervous system depressant or another medicine that increases levels of **SWICLONE®** Tablet in your blood, or while drinking alcohol. Do not engage in hazardous activities requiring complete mental alertness such as driving or operating machinery after taking **SWICLONE®** Tablet, and in particular during the 12 hours after taking your medicine. For more information about possible side effects which could affect your driving see section 8 of this leaflet.

SWICLONE® Tablets contain Lactose. If you have been told by your doctor that you have intolerance to Lactose, contact your doctor before taking this medicine

ADVERSE REACTIONS

Like all medicines, **SWICLONE®** Tablets can cause side effects, although not everybody gets them. Stop taking **SWICLONE®** Tablet 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.

Rare (may affect 1 in 1,000 people) Tell your doctor as soon as possible if you have any of the following side effects:

- Poor memory since taking **SWICLONE®** Tablet (amnesia). By having 7-8 hours of uninterrupted sleep after taking **SWICLONE®** Tablet, this is less likely to cause you a problem.
 - Seeing or hearing things that are not real (hallucinations)
 - Falling, especially in the elderly
 - Not Known (frequency cannot be estimated from the available data)
 - Thinking things that are not true (delusions)
 - Feeling low or sad (depressed mood)
- Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days

Common (may affect 1 in 10 people)

- . Feeling drowsy or sleepy
- . Dry mouth Uncommon (may affect up to 1 in 100 people)
- . Feeling sick (nausea) or being sick (vomiting)
- . Feeling dizzy
- . Headache
- . Nightmares
- . Feeling physically or mentally tired
- . Agitation Rare (may affect up to 1 in 1,000 people)
- . Feeling confused
- . Itchy, lumpy rash (urticaria)
- . Feeling irritable or aggressive
- . Reduced sex drive
- . Difficulty in breathing or being short of breath not known (frequency cannot be estimated from available data)
- . Feeling restless or angry
- . Feeling light headed or having problems with your coordination
- . Double vision
- . Moving unsteadily or staggering
- . Muscular weakness
- . Indigestion
- . Becoming dependent on **SWICLONE**[®] Tablet
- . Slower breathing (respiratory depression)
- . Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)
- . Mental problems such as poor memory, Difficulty paying attention, disrupted normal speech

DRUGS ABUSE AND DEPENDENCE**Dependence:**

The use of benzodiazepines and benzodiazepine-like substances can lead to physical and psychological dependence on these agents. The risk of dependence increases the higher the dose and the longer the period of treatment. This risk is also higher in patients with a history of alcohol or drug abuse and/or those who have marked personality disorders.

Withdrawal Treatment should be gradually withdrawn. A transient syndrome whereby the symptoms that led to treatment with **SWICLONE**[®] Tablets reoccur in an enhanced form, may occur on withdrawal. It may be accompanied by other reactions including mood changes, anxiety and restlessness.

SYMPTOMS OF OVERDOSE AND ANTIDOTE

If you take more **SWICLONE**[®] Tablets than you should Contact your doctor or nearest hospital casualty department immediately for advice. Take the medicine pack with you. This is so the doctor knows what you have taken.

SWICLONE[®] Tablet overdosage can be harmful. The following effects may happen:

- . Feeling drowsy, confused, sleeping deeply and possibly falling in to a coma
- . Floppy muscles (hypotonia)
- . Feeling dizzy, light headed or faint. These effects are due to low blood pressure
- . Falling over or losing your balance (ataxia)
- . Shallow breathing or difficulty breathing (respiratory depression)

Recommended Treatment:

Symptomatic and supportive treatment in adequate clinical environment is recommended, attention should be paid to respiratory and cardiovascular functions. Gastric lavage or activated charcoal is only useful when performed soon after ingestion. Hemodialysis is of no value due to the large volume of distribution of **SWICLONE**[®] Tablet. Flumazenil may be a useful antidote; however, flumazenil administration may contribute to the appearance of neurological symptoms (agitation, anxiety, convulsions and emotional lability). Intravenous fluids should be administered as needed.

DOSAGE AND ADMINISTRATION

- . Swallow the tablet with water
- . Do not crush or chew your tablets
- . Take just before bedtime in a single intake and do not take again during the same night
- . The usual length of treatment is 2 days to 3 weeks

Adults:

The recommended starting dose is 7.5 mg **SWICLONE**[®] Tablet just before bedtime. This dose should not be exceeded.

Elderly:

The usual starting dose is 3.75 mg - half tablet of Swiclone tablet just before bed time. Your doctor may decide to increase your dose to one **SWICLONE**[®] Tablets (7.5 mg) if needed.

Patients with liver, respiratory or kidney problems: The usual starting dose is half of **SWICLONE**[®] Tablets (3.75 mg) just before bedtime.

Children and adolescents:

SWICLONE[®] Tablet should not be used for children and adolescents less than 18 years. The safety and efficacy of **SWICLONE**[®] Tablet in children and adolescents aged less than 18 years have not been established.

Blood Tests

SWICLONE[®] Tablets can change the levels of liver enzymes shown up in blood tests. This can mean that your liver is not working properly

* If you are going to have a blood test, it is important to tell your doctor that you are taking **SWICLONE**[®] Tablets.

If you forget to take SWICLONE[®] Tablets

SWICLONE[®] Tablet 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 the double dose to make up for a forgotten dose.

Do not stop taking **SWICLONE**[®] Tablet 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 **SWICLONE**[®] Tablet 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, shaky, irritable, agitated, confused or having panic attacks
- . Sweating
- . Headache
- . Faster heartbeat or uneven heartbeat (palpitations)
- . A lower level of awareness and problems with focusing or concentrating
- . Nightmares, seeing or hearing things that are not real (hallucinations)
- . Being more sensitive to light, noise and touch than normal
- . Relaxed grip on reality
- . Numbness and tingling in your hands and feet
- . Aching muscles
- . Stomach problems In rare cases fits (seizures) may also occur. If you have any further questions on the use of this product, ask your doctor or pharmacist

PRESENTATION

SWICLONE[®] 7.5 mg tablets are white coloured, oval, film-coated tablets with a score line on one side.

The tablets are available in a pack size of 1 x 14 and 2 x 14 Tablets.

STORAGE CONDITION

- . Store below 25° C. Store in the original package in order to protect from moisture and light.
- . Do not use this medicine after the expiry date (EXP.) which is stated on the pack. The expiry date refers to the last day of that month.
- . Do not throw away any medicine via wastewater or house hold waste. Ask your pharmacist how to throw away any medicine you no longer use. These measures will help protect the environment

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN**Manufactured by:**

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