

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

Nocturno 3.75

Nocturno Forte 7.5

Tablets

Composition:

Each **Nocturno 3.75** tablet contains: Zopiclone 3.75 mg

Each **Nocturno Forte 7.5** tablet contains: Zopiclone 7.5 mg

For information on the inactive and allergenic ingredients in the preparation, see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

This medicine is not intended for children and adolescents under the age of 18 years.

1. WHAT IS THE MEDICINE INTENDED FOR?

Nocturno is intended for the treatment of the following severe sleep disorders:

a. Transient insomnia. b. Short-term insomnia.

Therapeutic group: Hypnotic and sedative from the cyclopyrrolone group.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (see section 6 "Further information"). Signs of allergic reaction include: rash, problems with swallowing or breathing, swelling of the lips, face, throat or tongue.
- You suffer from a disease that causes severe muscle weakness (myasthenia gravis).
- You suffer from a problem in lung function (respiratory insufficiency).
- You suffer from a problem in which you stop breathing for short periods at night (sleep apnea).
- You suffer from severe liver problems.
- You are below the age of 18 years. This is because the efficacy and safety of **Nocturno** in children and adolescents under the age of 18 years have not yet been determined.
- You have experienced sleepwalking or any other unusual behavior in the past (such as driving, eating, making a phone call or having sex, etc.) while you are not fully awake after taking **Nocturno**.

Do not take this medicine if any of the above conditions apply to you. If you are uncertain, talk to your doctor or pharmacist before taking **Nocturno**.

Special warnings regarding use of the medicine

Before treatment with Nocturno, tell the doctor if:

- You suffer from any liver problems (also see in section 2 “Do not use the medicine if”). The doctor may need to give you a reduced dosage of **Nocturno**.
- You suffer from any kidney problems. The doctor may need to give you a reduced dosage of **Nocturno**.
- You suffer from mild breathing problems. The doctor will decide if you should receive **Nocturno** (see also in section 2 “Do not use the medicine if”).
- You have had a mental disorder (including depression and personality disorder) or you have abused or were dependent on alcohol or drugs.
- You have recently used **Nocturno** or other similar medicines for more than 4 weeks.

Risk of abuse and dependence

Use of **Nocturno** may lead to the development of abuse and/or physical and psychological dependence. The risk of dependence increases with dose and duration of treatment and is greater when the treatment duration with **Nocturno** is longer than 4 weeks, and in patients with a history of mental disorders and/or alcohol, illicit substances or drug abuse.

The medicine is not intended for treatment of depression.

Nocturno and mental health

Some people being treated with **Nocturno** may experience mental health problems such as thoughts about things that are not real (delusions), seeing or hearing things that are not there (hallucinations), feeling confused or disorientated (delirium), feeling angry, irritable, restless or depressed.

Additionally, several studies have shown an increased risk of suicidal thoughts, suicidal attempt and suicide in patients taking certain sedatives and medicines for sleep problems, including this medicine. However, it has not been determined whether it was caused by the medicine or if there may be other causes. **If you have suicidal thoughts, refer to your doctor as soon as possible for further medical advice.**

Nocturno and unusual behavior

Nocturno may cause sleepwalking or other unusual behavior (such as driving, eating, making a phone call, or having sex, etc.) while you are not fully awake. The next morning, you may not remember that you did anything during the night. These activities may occur whether or not you drink alcohol or take other medicines that make you drowsy together with **Nocturno**. If you experience any of the aforementioned effects, stop the treatment with **Nocturno** immediately and contact your doctor or healthcare provider.

Before taking **Nocturno**, it is important to make sure that you will be able to sleep at least 7 to 8 consecutive hours, to help lower the risk of certain side effects (see section 4 “Side effects”).

If you are uncertain if any of the above conditions apply to you, talk to your doctor or pharmacist before taking **Nocturno**.

Children and adolescents

This medicine is not intended for children and adolescents under the age of 18 years.

Tests and follow-up

Nocturno may change the liver enzyme levels that appear in blood tests. This may indicate that your liver is not working properly.

If you are going to have blood tests, it is important to tell your doctor that you are taking **Nocturno**.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. This is because **Nocturno** may affect the activity of certain other medicines. Similarly, certain medicines may affect the activity of **Nocturno**. In particular, if you are taking:

Nocturno may increase the effect of the following medicines:

- Medicines for the treatment of mental diseases (antipsychotics).
- Medicines to treat depression.
- Medicines to treat epilepsy (anticonvulsants).
- Medicines used in surgeries (anesthetics).
- Medicines to calm (sedatives), to reduce anxiety or medicines for sleep problems (hypnotics).
- Medicines to treat hay fever, rashes or other allergies, which may cause you to be sleepy (sedating antihistamines), such as chlorphenamine or promethazine.
- Certain moderate to strong painkillers (narcotic analgesics) such as codeine, methadone, morphine, oxycodone, pethidine or tramadol.

The following medicines may increase the chance of side effects if taken together with **Nocturno**. To reduce the chance, the doctor may decide to lower the **Nocturno** dosage that you are taking:

- Certain antibiotics such as clarithromycin or erythromycin.
- Certain medicines to treat fungal infections, such as ketoconazole or itraconazole.
- Ritonavir (from the protease inhibitor family) to treat HIV infection.
- Concomitant use of **Nocturno** and opioids increases the risk of drowsiness, breathing difficulties, coma and death. **Nocturno** and opioids should only be used concomitantly, when other treatment options are inadequate. Please tell your doctor about all opioid medicines you are taking and follow the doctor's dosage recommendations closely.

The following medicines may reduce the effect of **Nocturno**:

- Certain medicines to treat epilepsy, such as carbamazepine, phenobarbital or phenytoin.
- Rifampicin (an antibiotic) to treat infections.
- St. John's wort (a herbal medicine) to treat mood swings and depression.

Use of the medicine and alcohol consumption

Do not drink alcohol when using **Nocturno**. Alcohol may increase the effect of the medicine and cause you to sleep very deeply, so that you will not breathe properly or will have difficulty waking up.

Pregnancy, breastfeeding and fertility

Pregnancy

Use of **Nocturno** during pregnancy is not recommended. If you are pregnant, think you may be pregnant or are planning to become pregnant, consult your doctor before taking the medicine.

If used during pregnancy, there is a risk that the baby will be affected. Some studies have shown that there might be an increased risk of a cleft lip and palate (sometimes called “hare-lip”) in the newborn.

Reduced fetal movements and changes in fetal heart rate may occur after taking **Nocturno** during the second and/or third trimester of pregnancy.

If **Nocturno** is taken at the end of the pregnancy or during delivery, your baby may exhibit muscle weakness, reduced body temperature, difficulty feeding and breathing problems (respiratory depression).

If this medicine is taken regularly in the late stages of pregnancy, your baby may develop physical dependence and may be at risk of developing withdrawal symptoms such as agitation or tremors. In such a case, monitor the newborn closely during the postpartum period.

Breastfeeding

Do not take **Nocturno** if you are breastfeeding or planning to breastfeed since small amounts may pass into the breast milk.

If you are breastfeeding or are planning to breastfeed, consult the doctor or pharmacist before using any medicine.

If you are pregnant or breastfeeding, consult the doctor or pharmacist before using any medicine.

Driving and operating machinery

Like other medicines for sleep problems, **Nocturno** can cause slowing of normal brain functioning (depression of the central nervous system).

The risk of psychomotor impairment, including impairment of the ability to drive, is increased if:

- You are performing activities that require alertness within 12 hours of taking **Nocturno**.
- You are taking a higher than recommended dosage of **Nocturno**.
- You take **Nocturno** while you are already taking another central nervous system depressant or another medicine that increases the levels of **Nocturno** in your blood, or while drinking alcohol.

Do not perform dangerous activities that require full alertness, such as driving or operating machinery, after taking **Nocturno**, especially during 12 hours after taking **Nocturno**.

For further information about possible side effects that may affect driving, see section 4 “Side effects”.

Important information about some of the ingredients of the medicine

Nocturno contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to certain types of sugars, consult the doctor before starting to use the medicine (see also section 6 “Further information”).

Nocturno contains sodium

Nocturno contains less than 1 mmol (23 mg) sodium per tablet, namely, the tablet is essentially “sodium-free”.

3. HOW SHOULD YOU USE THE MEDICINE?

The treatment should be as brief as possible and should not exceed 4 weeks (including the discontinuation phase).

Always use the preparation according to the doctor’s instructions.

Check with the doctor or pharmacist if you are unsure about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

Adults

The usual dosage is one tablet of **Nocturno Forte 7.5** (7.5 mg) immediately before bedtime.

Elderly

The usual starting dosage is one tablet of **Nocturno 3.75** (3.75 mg) immediately before bedtime. Later on, the dosage may be increased, as necessary.

Be careful and lean on something when getting out of bed!

Children and adolescents

This medicine is not intended for use in children and adolescents below the age of 18. The efficacy and safety of **Nocturno** in children and adolescents under the age of 18 have not yet been determined.

Patients with liver, breathing, or kidney problems

The usual starting dosage is one tablet of **Nocturno 3.75** (3.75 mg) immediately before bedtime.

Do not exceed the recommended dosage!

Treatment duration

The usual duration of treatment is two days to 3 weeks.

Taking the medicine

- Swallow the medicine with water.
- Do not halve, crush or chew the tablets.
- Take the required dose of **Nocturno** as a single dose, and do not take an additional dose the same night.
- Take the preparation when you are in bed, just before going to sleep, and make sure that you will be able to sleep 7-8 hours without interruption.

If you took a higher dosage or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

Taking an overdose of **Nocturno** is very dangerous. You may suffer from the following effects:

- A sensation of drowsiness, confusion, deep sleep and possibly even coma.
- Floppy muscles (hypotonia).
- Feeling of dizziness, lightheadedness or faintness. These effects are due to low blood pressure.
- Falls or loss of balance (ataxia).
- Shallow breathing or difficulties in breathing (respiratory depression).

If you forgot to take the medicine

Nocturno should only be taken before bedtime.

If you forgot to take the medicine just before going to sleep, do not take the medicine at any other time. Otherwise, you may feel drowsy, dizzy and confused during the day.

Never take two doses together in place of the forgotten dose!

If you stop taking the medicine

Continue taking **Nocturno** until your doctor tells you to stop. Do not stop taking **Nocturno** suddenly; but tell your doctor if you intend to stop the treatment. Your doctor will need to lower your dosage and stop the treatment gradually over a period of time.

If you stop treatment with **Nocturno** suddenly, sleep disorders may come back, and you may suffer from withdrawal effects.

If this happens, you may suffer from some of the effects listed below.

Refer to a doctor immediately if you suffer from any of the following effects:

- Feel anxious, unsteady, nervous, agitated, confused or you have panic attacks.
- Sweating.
- Headache.
- Faster or irregular heartbeats (palpitations).
- A low level of alertness and problems concentrating and focusing.
- Nightmares, seeing or hearing things that are not real (hallucinations).
- Hypersensitivity to light, noise and touch.
- Poor reality perception.
- Numbness and tingling in the hands and feet.
- Muscle pains.
- Abdominal problems.

In rare cases, fits (convulsions) may also occur.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of **Nocturno** may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Stop treatment with the medicine and refer to a doctor or proceed to a hospital immediately if:

You are suffering from an allergic reaction to **Nocturno**. Signs could include: rash, swallowing or breathing difficulties, swelling of the lips, face, throat or tongue.

Refer to the doctor immediately if you notice any of the following side effects:

Rare side effects (effects that occur in 1-10 users out of 10,000):

- Memory impairment since taking **Nocturno** (forgetfulness). You can reduce the chance for this effect if you make sure that you have 7-8 hours of continuous and uninterrupted sleep after taking **Nocturno**.
- Seeing or hearing things that are not real (hallucinations).
- Falls, mainly among the elderly.

Side effects of unknown frequency (effects whose frequency has not been determined yet):

- Thoughts about things that are not real (delusions).
- Feeling sad or depressed (low mood).

Refer to the doctor or pharmacist if one of the following effects worsens or persists for more than a few days:

Common side effects (effects that occur in 1-10 users out of 100):

- Bitter or metallic taste in the mouth or dry mouth.
- Feeling drowsy or sleepy.

Uncommon side effects (effects that occur in 1-10 users out of 1,000):

- Nausea or vomiting.
- Feeling dizzy or sleepy.
- Headache.
- Nightmares.
- Feeling physically or mentally tired.
- Nervousness.

Rare side effects (effects that occur in 1-10 users out of 10,000):

- Feeling confused.
- Itchy, lumpy rash (urticaria).
- Feeling irritable or aggressive.
- Decreased libido.
- Difficulty breathing or shortness of breath.

Side effects of unknown frequency (effects whose frequency has not been determined yet):

- Feeling restless or angry.
- Feeling dizzy or having coordination problems.
- Double vision.
- Unsteady or staggering movements.
- Muscle weakness.
- Digestive disorder.
- Development of dependence on **Nocturno**.
- Slower breathing (respiratory depression).
- Unusual skin sensations such as numbness, tingling, prickling, burning or paresthesia.
- Mental disturbances such as impaired memory.
- Difficulty concentrating.
- Speech disorder.
- **Nocturno** may cause sleepwalking or other unusual behavior (such as driving, eating, making a phone call, or having sex, etc.) while you are not fully awake.

- Delirium (a sudden and severe change in mental state that can cause a combination of confusion, disorientation and/or attention deficit).

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects or by entering the link:

<https://sideeffects.health.gov.il>

Additionally, you can report to “Unipharm Ltd.”.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C, and in a place protected from light.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Dibasic Calcium Phosphate (anhydrous); Lactose (anhydrous); Maize Starch; Sodium Starch Glycolate; Magnesium Stearate; Opadry.

Each **Nocturno 3.75** tablet contains 21.0 mg lactose.

Each **Nocturno Forte 7.5** tablet contains 42.0 mg lactose.

What the medicine looks like and contents of the package:

The medicine is packaged in trays (blisters) inserted into a carton package. Each package of **Nocturno 3.75** has 7, 10, 14, 15, 20 or 30 tablets. Not all package sizes may be marketed.

Each package of **Nocturno Forte 7.5** has 7, 10, 14, 20, 21 or 28 tablets. Not all package sizes may be marketed.

Nocturno 3.75 are round, biconvex, orange film-coated tablets.

Nocturno Forte 7.5 are round, biconvex, yellow film-coated tablets.

Registration holder and address: Unipharm Ltd.,

P.O. Box 21429, Tel Aviv, 6121301.

Manufacturer and address: Unipharm Ltd., “Mevo Carmel” Industrial Park.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Nocturno 3.75: 121 81 30138 01

Nocturno Forte 7.5: 111 24 29356 01

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