

**Patient Leaflet in Accordance with the Pharmacists' Regulations**  
**(Preparations) – 1986**

This medicine is sold with a doctor's prescription only

**OxyContin 10, 20, 40, 80**  
**Controlled-release tablets**

**Active ingredient:**

Each tablet of **OxyContin 10** contains: 10 mg oxycodone hydrochloride.

Each tablet of **OxyContin 20** contains: 20 mg oxycodone hydrochloride.

Each tablet of **OxyContin 40** contains: 40 mg oxycodone hydrochloride.

Each tablet of **OxyContin 80** contains: 80 mg oxycodone hydrochloride.

For the list of the additional ingredients, see section 6.

**Read the entire leaflet carefully before using the medicine.**

This leaflet contains concise information about the medicine. If you have any further questions, please refer to the doctor or pharmacist.

This medicine was prescribed to treat your condition. Do not pass it on to others. It may harm them, even if you think their medical condition is similar to yours.

Medicines of the opioids group may cause addiction, especially with prolonged use, and they have a potential for misuse and overdose. A reaction to an overdose may be manifested in slow breathing and may even cause death.

Make sure you know the name of the medicine, the dosage that you take, how often you take it, the duration of treatment, potential side effects and risks.

Additional information regarding the risk of dependence and addiction can be found at the following link:

[https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/risk/DocLib/opioids\\_en.pdf](https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/risk/DocLib/opioids_en.pdf)

Taking this medicine along with medicines from the benzodiazepines group, other medicines that depress the central nervous system (including drugs) or alcohol may cause a feeling of profound drowsiness, breathing difficulties (respiratory depression), coma and death.

**1. What is the medicine intended for?**

The medicine is intended for the relief of long-term moderate to severe pain.

**Therapeutic Group:** Opioid analgesics

This medicine has been prescribed for you only and should not be given to anyone else. Opioids may cause addiction, and you may experience withdrawal symptoms if you stop taking them suddenly. Make sure you received an explanation from the doctor on the duration of treatment with the medicine, when it is appropriate to stop taking it, and how to do so safely.

**2. Before using the medicine**

**Do not use the medicine if:**

- You are sensitive (allergic) to the active ingredient (oxycodone hydrochloride) or to any of the additional ingredients the medicine contains (for the list of the additional ingredients, see section 6).

- You suffer from breathing problems such as severe chronic obstructive pulmonary disease, severe bronchial asthma, severe respiratory depression. The symptoms can include shortness of breath, coughing or breathing more slowly or weakly than expected.
- You suffer from a condition where the small intestine does not function properly (intestinal obstruction, suspected intestinal obstruction), slow gastric emptying, severe abdominal pain, chronic constipation.
- You suffer from a heart problem after long-term lung disease (cor pulmonale).
- You suffer from a high carbon dioxide level in your blood. The symptoms may include dizziness, drowsiness, fatigue, shortness of breath and headache.
- You suffer from a moderate to severe liver problem. If you suffer from other long-term liver problems, you should consult with the doctor.
- You suffer from severe impairment in kidney function.
- Do not use OxyContin 80 if you are not used to taking opioid medicines.
- Do not use OxyContin 10, 20, 40 and 80 in children and adolescents under the age of 18.

### **Special warnings regarding the use of this medicine:**

#### **Before (and during) treatment with OxyContin inform your doctor if:**

- You or someone in your family suffers or has ever suffered from opioids, alcohol, medicines or drugs addiction.
- You are a smoker.
- You ever had problems with your mood (depression, anxiety, personality disorder), or if you suffered in the past from other mental problems that were treated by a psychiatrist.
- You have suffered in the past from withdrawal symptoms such as: agitation, anxiety, shaking, or sweating as a result of stopping the use of alcohol, medicines or drugs.
- You feel you need to take more tablets to reach the same level of pain relief. This phenomenon may be a sign that you are developing tolerance to the effects of the medicine or are becoming addicted to it. In this case contact the doctor in order to discuss the treatment and evaluate whether a change in dosage or replacement of the medicine with another pain reliever is necessary.
- You are elderly or weakened.
- You suffer from an underactive thyroid gland (hypothyroidism), as you may need a lower dose.
- You suffer from myxedema which is a problem of the thyroid gland manifested in dryness, cold, puffy and swollen skin and affects the face and limbs.
- You suffer from a brain injury or tumor, a head injury, increased pressure in the skull (which may be expressed in severe headaches and nausea).
- You suffer from low blood pressure, or low blood volume (which can happen as a result of severe internal or external bleeding, severe burns, excessive sweating, severe diarrhea or vomiting).
- You feel very dizzy, a feeling of faintness or reduction in the level of consciousness.
- You suffer from a mental problem as a result of the use of certain medicines (toxic psychosis), alcoholism or delirium tremens (a psychosis caused upon withdrawal from alcohol).
- You suffer from inflammation in the pancreas (which causes severe pain in the abdomen and back); problems in the gallbladder or biliary tract; inflammatory bowel disease; enlargement of the prostate gland causing difficulty urinating (in

men); impaired adrenal gland function (which may cause symptoms such as weakness, weight loss, dizziness, nausea, vomiting) such as in Addison's disease.

- You suffer from severely impaired lung function. The symptoms can include shortness of breath and coughing.
- You suffer from long-term pain unrelated to cancer.
- You suffer from a condition in which your breathing stops for a short time when you are sleeping, a condition called sleep apnoea.
- You suffer from kidney or liver problems. See also 'Do not use the medicine if'.
- You suffer or have suffered in the past from problems in the digestive system, such as narrowing, surgery, constipation, esophageal or intestinal cancer.

### **Additional warnings:**

Do not chew, crush, dissolve, halve or break the tablet.

Do not use the medicine if you cannot swallow the tablet whole. If you suffer from difficulty swallowing and particularly with swallowing tablets, inform the attending doctor before starting treatment with this medicine.

- OxyContin tablets contain oxycodone (an opioid substance) and have the potential for abuse. Do not give OxyContin to another person. Take all precautions in order to prevent the medicine from reaching somebody who is not the patient.
- Long-term use may cause dependence!
- Taking this medicine regularly, particularly for a long period, may cause addiction. This may cause a life-threatening overdose. If you fear that you might become dependent on the medicine, it is important you consult your doctor. Make sure you received an explanation from the doctor on the duration of treatment with the medicine, when it is appropriate to stop taking it and how to do so safely.
- Addiction may cause withdrawal symptoms when you stop taking the medicine. Withdrawal symptoms may include restlessness, sleeping difficulties, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increase in blood pressure, nausea, vomiting, diarrhea, loss of appetite, shaking, shivering, sweating. Before discontinuing the medicine, consult with the doctor who will guide you how to gradually reduce the dosage. It is important to not stop taking the medicine suddenly since then the risk that you will experience withdrawal symptoms increases. See also in section 3 'If you stop taking the medicine'.
- Taking high or frequent doses of opioids increases the risk of developing an addiction. Overuse and abuse may lead to an overdose and even to death.
- Sleep-related breathing problems: The medicine can cause and/or worsen sleep-related breathing problems such as sleep apnoea (breathing pauses during sleep) and sleep-related hypoxemia (low oxygen level in the blood). Tell the doctor if you, or someone else in your surroundings, notice the following symptoms: breathing pauses during sleep, waking up because of shortness of breath, difficulty staying asleep, increased daytime drowsiness. In this case the doctor may recommend reducing the dosage.
- Do not inject the medicine. Injecting the medicine can cause serious side effects including tissue death at the injection site, infection, inflammation of the lungs and damage to the heart which can cause death.
- In rare cases, increasing the medicine dosage may cause you to be more sensitive to pain. In this case, contact the doctor for consultation regarding the treatment.

- If you recently underwent or are due to undergo surgery, or any procedure entailing anesthesia, tell your doctor that you are taking this medicine. The use is not recommended before surgery. It should be used with extreme caution for up to 24 hours after the surgery and according to the doctor's instructions (who may adjust the dosage).
- Avoid a sudden change from a lying/sitting position to standing, to avoid dizziness and in extreme cases fainting.
- You may experience hormonal changes during the treatment period with the medicine.

**Children and adolescents:** OxyContin 10, 20, 40 and 80 should not be used in children and adolescents under the age of 18 years.

**Tests and follow-up:**

- During long-term treatment, you should undergo periodic evaluations to assess the ongoing need for the medicine.
- The doctor may monitor possible hormonal changes.

**Drug interactions:**

**Taking OxyContin concomitantly with other medicines that depress the central nervous system** can cause slow breathing or breathing difficulties (respiratory depression), severe drowsiness, loss of consciousness/coma and death. For this reason the doctor will consider the concomitant use of OxyContin with these medicines, only if no other treatment options exist and only in low dosage and for short periods of time. These medicines include: other opioid medicines for pain relief (such as morphine or codeine); gabapentinoids (for treatment of epilepsy) such as pregabalin; anti-anxiety medicines; sedatives, tranquilizers, medicines to induce sleep (such as benzodiazepines); medicines for the treatment of psychiatric/mental problems (such as phenothiazines); antidepressants, anesthetics; muscle relaxants; medicines for the treatment of high blood pressure; medicines from the monoamine oxidase inhibitors group (MAOIs) used for instance for the treatment of depression, such as tranylcypromine, phenelzine, isocarboxazid. Do not use OxyContin if you are taking medicines from the MAOIs group or have taken them in the last two weeks.

If you or those around you (friends, family, caregivers) notice that you are having difficulty breathing or have become very drowsy or lost consciousness, refer to a doctor **immediately**.

**Taking OxyContin concomitantly with medicines used for the treatment of depression from the SSRIs or SNRIs group (Selective Serotonin/Norepinephrine Reuptake Inhibitors) or other serotonergic**

**medicines may cause serotonin toxicity.** The symptoms include: changes in your mental state such as agitation, seeing or hearing things that do not exist in reality (hallucinations), loss of consciousness/coma; rapid heartbeats, changes in blood pressure, increase in body temperature, muscle spasms, lack of coordination, exaggeration of reflexes, stiffness; digestive system symptoms such as nausea, vomiting, diarrhea. If you are taking medicines from the SSRIs or SNRIs group such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline or venlafaxine, the doctor may reduce the dosage. Contact the doctor if you experience these symptoms.

**If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell the doctor or**

**pharmacist.** The doctor may adjust the dosage of the medicines. Especially inform the doctor or pharmacist if you are taking the following medicines:

- Certain antidepressants from the tricyclic group such as amitriptyline, clomipramine, imipramine, lofepramine, nortriptyline.
- Medicines for the treatment of allergies (antihistamines) such as cetirizine, fexofenadine, chlorphenamine.
- Medicines for the treatment of Parkinson's disease.
- Antibiotics from the macrolide group such as clarithromycin, erythromycin, telithromycin.
- Antifungals such as: ketoconazole, voriconazole, itraconazole, posaconazole.
- Medicines against the HIV virus from the protease inhibitors group, such as boceprevir, ritonavir, indinavir, nelfinavir, saquinavir.
- Cimetidine (a medicine for the treatment of a stomach ulcer).
- Rifampicin (for the treatment of tuberculosis).
- Medicines for the treatment of fits/convulsions/seizures such as carbamazepine and phenytoin.
- The hypericum plant (also known as St. John's Wort) used for the treatment of depression.
- Quinidine (for treatment of irregular heartbeats).
- Anticholinergics or medicines with an anticholinergic activity.

#### **Use of this medicine and food:**

- The medicine can be taken regardless of mealtimes.
- Avoid grapefruits during the treatment period with the medicine.

#### **Use of this medicine and alcohol consumption:**

Do not drink alcohol during the treatment period with this medicine.

Drinking alcohol during the treatment period with the medicine may cause you to feel drowsier or increase the risk of serious side effects, such as shallow breathing with a risk of breathing cessation and loss of consciousness.

#### **Pregnancy and breastfeeding:**

- **Pregnancy:** Do not use the medicine if you are pregnant or if you think you are pregnant, unless the doctor decided that the benefit of use of the medicine outweighs the possible risk. If the medicine is taken during pregnancy, the baby may develop dependence on the medicine and experience withdrawal symptoms after birth, which may need to be treated. The symptoms may include: agitation, hyperactivity, abnormal sleeping patterns, high-pitched crying, tremor, vomiting, diarrhea, lack of weight gain.
- **Childbirth:** The use is not recommended during childbirth. Use during childbirth may cause respiratory depression in the newborn.
- **Breastfeeding:** Do not use the medicine during the breastfeeding period since the active ingredient (oxycodone) passes into breastmilk and can affect the baby (may cause respiratory depression in the baby).

**Driving and use of machinery:** The use of this medicine may cause some side effects that could impair your ability to drive or operate machinery (for instance, drowsiness, dizziness). See section 4 for the complete list of side effects. Usually, these side effects are felt more at the beginning of the treatment and/or with a dosage increase. If you feel these effects and/or any other effect which may affect driving, do not drive or operate machinery. Do not drive until you know how the

medicine affects you. If you have any doubts whether driving is safe for you during the treatment period, consult with the doctor or the pharmacist.

### 3. How should you use the medicine?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine. The dosage and manner of treatment will be determined by the doctor only.

Make sure that the prescribing doctor discussed with you the duration of treatment with the medicine, a plan for discontinuing the treatment, and how to gradually stop taking the medicine.

#### **The standard dosage is usually:**

The starting dose is usually 10 mg every 12 hours. Take the medicine at set times (every 12 hours, for instance, at 8 a.m. and 8 p.m.), as determined by the attending doctor. Do not use this medicine more frequently. The doctor will adjust your dosage according to your condition and the intensity of your pain.

Do not change the dosage without consulting with the attending doctor. If, during treatment with the medicine, you continue to experience pain, refer to the doctor. In addition, you should also inform the attending doctor if you experience instances of breakthrough pain.

**Patients with kidney or liver problems:** Tell the doctor if you suffer from kidney or liver problems. The doctor may prescribe a lower dose depending on your condition.

**Do not exceed the recommended dose.**

The tablets are intended to be administered by mouth only. Swallow the medicine with water. Do not retain the tablet in your mouth beyond the time necessary to swallow it.

The OxyContin tablets have an extended-release mechanism. When the tablet is swallowed whole, the active ingredient should have an effect for 12 hours.

**Swallow the tablet whole, so that you do not damage the extended-release mechanism of oxycodone from the tablet. Do not break, chew, crush, dissolve or halve the tablet! Taking tablets that are not whole may lead to more rapid absorption of oxycodone and cause serious side effects and overdose that could cause death (see section 'if you have accidentally taken a higher dosage').**

Do not crush and inject the tablets since this may lead to serious side effects and even death. *See also 'Additional Warnings' in section 2.*

#### In order to reduce the risk of choking on the tablet:

- Do not wet or lick the tablet before placing it in your mouth.
- Make sure to swallow each tablet separately (even in cases when the doctor instructed you to take more than one tablet per dose) with enough water to guarantee complete and immediate swallowing of the tablet.

The active ingredient is released gradually from the tablet during the time that it is in your body and the tablet's empty matrix may be excreted in your stool. This phenomenon is not a cause for concern since the active ingredient was already absorbed in the body.

**If you have accidentally taken a higher dosage** or if a child or any other person has accidentally swallowed the medicine, proceed **immediately** to a doctor or hospital emergency room and bring the package of the medicine. An overdose may

cause you to feel very sleepy as well as cause symptoms such as: nausea/vomiting, dizziness, hallucinations, decrease in blood pressure, constricted pupils, decrease in muscle tone (hypotonia), bradycardia (slow heart rate). In addition, pulmonary edema, breathing difficulties (up to respiratory depression), cardiovascular collapse may also appear, which may cause a loss of consciousness/coma and even death. These symptoms require urgent medical care in a hospital. You should ask the people around you to be familiar with these symptoms as well and pay attention if they appear by you.

#### **If you forgot to take the medicine:**

If you remember within 4 hours from the time when you should have taken the medicine, take it immediately. Take the next dose at the usual time.

If more than 4 hours have elapsed from the time when you should have taken the medicine, consult the doctor.

Do not take a double dose to compensate for the forgotten dose.

Adhere to the treatment as recommended by the doctor.

Even if your state of health improves, do not stop the treatment with the medicine without consulting the doctor, and even then, usually only in a gradual manner.

**If you stop taking the medicine:** Do not stop taking the medicine suddenly. If you want to stop taking the medicine, first consult your doctor who will instruct you how to do this. The doctor will usually recommend that you gradually reduce the dosage in order to reduce the risk of the appearance of withdrawal symptoms such as: agitation, restlessness, sleeping difficulties, irritability, anxiety, feeling your heartbeat (palpitations), increase in blood pressure, nausea, vomiting, diarrhea, shaking, shivering, sweating, tearing, runny nose, yawning, muscle pain, dilated pupils, hyperactivity, weakness, abdominal cramps, loss of appetite, anorexia, increased heart and/or breathing rate.

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

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

## **4. Side effects**

As with any medicine, the use of OxyContin may cause side effects in some users.

Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

#### **Proceed immediately to a doctor or a hospital emergency room if the following side effects appear:**

- **Allergic or anaphylactic reaction.** Any medicine can cause an allergic reaction, although a serious allergic reaction is rare. Symptoms of a serious allergic reaction can include sudden wheezing, breathing difficulties, swelling of the face, eyelids or lips; rash and/or itching (particularly in large areas of the body).
- **Respiratory depression.** The most serious side effect is a condition where you breathe more slowly or weakly than usual, which can lead to severe sleepiness and loss of consciousness. This side effect may affect up to 1 out of 100 people and is more likely to occur when used concomitantly with certain other medicines (see also 'Drug interactions' in section 2). It is recommended to ask

those around you (friends, family, caregivers) to pay attention whether you develop these signs and symptoms.

- **Withdrawal symptoms:** When you stop taking the medicine, you may experience withdrawal symptoms. See 'If you stop taking the medicine' in section 3.
- **Difficulties swallowing the tablet,** including situations in which the tablet gets stuck in your throat and/or causes choking.

**Addiction: How to identify a state of addiction?**

Symptoms of addiction can include: a feeling that you need to take the medicine for a longer time period than recommended by the doctor and/or take a higher dose than that recommended by the doctor; use of the medicine for reasons other than those for which it was prescribed for you; when you stop taking the medicine you feel unwell, and you feel better when you take the medicine again. If you experience these symptoms refer to the doctor.

**Additional side effects:**

*Very common side effects (appear in more than 1 user out of 10):*

Constipation (the doctor can prescribe a laxative to overcome this problem); nausea and/or vomiting (these effects usually pass after a few days, but the doctor can prescribe an anti-nausea/vomiting medicine if the problem continues); drowsiness (usually appears when you start using the medicine or when the dosage is increased, but passes generally after a few days); dizziness; headache; skin itchiness.

*Common side effects (appear in 1-10 users out of 100):*

Dry mouth, decrease in appetite (up to loss of appetite), digestion difficulties, abdominal pain or abdominal discomfort, diarrhea; confusion, depression, unusual weakness, shaking, lack of energy, tiredness, sedation, anxiety, nervousness, sleeping difficulties, unusual dreams and thoughts; breathing difficulties, wheezing, shortness of breath, bronchospasm, decrease in the cough reflex; rash, sweating (including excess sweating).

*Uncommon side effects (appear in 1-10 users out of 1,000):*

Withdrawal symptoms; swallowing difficulties, belching, hiccups, wind, improper bowel activity (intestinal blockage, ileus), inflammation of the stomach, changes in taste or unpleasant taste; vertigo (dizziness or feeling of spinning), hallucinations, mood changes, despondency, feeling of extreme happiness (euphoria), disorientation, restlessness, agitation, generally feeling unwell, memory loss, difficulty speaking, reduced sensitivity to pain or touch, tingling or numbness, seizures, convulsions, blurred vision or impaired vision, fainting, unusually rigid or lax muscles, involuntary muscle contractions; muscle spasms; pain or difficulty when urinating (including urinary retention), impotence, decrease in sexual drive, low level of sex hormones, as seen in blood tests (hypogonadism); rapid and/or irregular heartbeat, palpitations, dilation of blood vessels, skin redness; dehydration, thirst, chills, swelling of the hands, ankles or feet, edema; dry skin, severe flaking or peeling of the skin; redness of the face (blushing), decrease in eye pupils size, fever; a need to take increasingly higher doses of the medicine to obtain the same level of pain relief (tolerance to the medicine); colicky abdominal pain and/or discomfort (which may be as a result of bile problems); worsening of liver functions (seen in blood tests, e.g.: increase in liver enzymes).

*Rare side effects (appear in 1-10 users out of 10,000):*



Low blood pressure, feeling faint (especially upon standing up); raised, itchy rash (urticaria/hives).

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

Dependency and addiction (see above – ‘How to identify a state of addiction’), hypersensitivity to pain, aggression, tooth decay, lack of menstrual period in women, obstruction of bile flow from the liver (may be manifested by itchy skin, yellowing of the skin, dark urine, pale stool); sleep apnoea (pauses in breathing during sleep); withdrawal symptoms that could be life-threatening in babies born to mothers who took the medicine for a long period during pregnancy (see also section 2 ‘Pregnancy and breastfeeding’).

**If a side effect appears, if one of the side effects worsen, or if you suffer from a side effect not mentioned in the leaflet, consult your doctor.**

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) that leads to an online form for reporting side effects, or by entering the link:

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

## 5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Accidental swallowing of an overdose by children is dangerous and may cause death. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- When you no longer need the tablets, consult the pharmacist on how to dispose of them.
- 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.
- Do not take broken or crushed tablets since this may be dangerous and may cause serious problems such as overdose.

## 6. Additional information

- **In addition to the active ingredient, the tablets also contain:**  
Polyethylene oxide, magnesium stearate, hypromellose, titanium dioxide, macrogol.

In addition,

Each tablet of **OxyContin 10** contains: Hydroxypropyl cellulose.

Each tablet of **OxyContin 20** contains: Polysorbate 80, red iron oxide (E172).

Each tablet of **OxyContin 40** contains: Polysorbate 80, yellow iron oxide (E172).

Each tablet of **OxyContin 80** contains: Hydroxypropyl cellulose, indigo carmine (E132), yellow iron oxide (E172)

- **What does the medicine look like and what does the package contain?**  
**OxyContin 10:** round white tablets in blister packs of 20 tablets.  
**OxyContin 20:** round pink tablets in blister packs of 20 tablets.  
**OxyContin 40:** round yellow tablets in blister packs of 20 tablets.  
**OxyContin 80:** round greenish tablets in blister packs of 20 tablets.

**Manufacturer and registration holder:** Rafa Laboratories Ltd., P.O. Box 405,  
Jerusalem 9100301

**Medicine registration number in the National Medicines Registry of the Ministry  
of Health:**

**OxyContin 10:** 1007128431

**OxyContin 20:** 1007028432

**OxyContin 40:** 1090129255

**OxyContin 80:** 1089829256

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