

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: Oxycodone hydrochloride 10 mg
 Each tablet of **OxyContin 20** contains: Oxycodone hydrochloride 20 mg
 Each tablet of **OxyContin 40** contains: Oxycodone hydrochloride 40 mg
 Each tablet of **OxyContin 80** contains: Oxycodone hydrochloride 80 mg

For list of inactive ingredients, please see section 6.

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist.

This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them, even if you think that their illness is the same as yours.

1. What is the medicine intended for?

This medicine is intended for the relief of moderate or severe continuous pain.

Therapeutic group: Opioid analgesics

2. Before you take the medicine:

Do not use the medicine if:

- Do not use if you are sensitive (allergic) to the active ingredient, to other opioids or to any of the other ingredients of this medicine (for list of inactive ingredients, please see section 6).
- Do not use if you suffer from respiratory depression, severe bronchial asthma, hypercapnia (excess carbon dioxide in the blood) or from severe lung function impairments, e.g. COPD.
- Do not use if you suffer from a failure of the right side of the heart (a condition known as cor pulmonale, manifested by pulmonary hypertension and enlargement of the right ventricle).
- Do not use if you suffer from severe kidney impairment or from moderate to severe liver impairment.
- Do not use if you suffer from intestinal obstruction, suspected intestinal obstruction, severe abdominal pain, delayed gastric emptying, chronic constipation.
- Do not use if you suffer from a head injury, or if you are about to undergo surgery or if you have undergone surgery in the past 24 hours.
- Do not use this medicine if you are currently taking a medicine of the monoamine oxidase inhibitors (MAOIs) group or if you have taken this type of medicine within the last two weeks.
- Do not use OxyContin 80 if you are not used to taking opioid medicines.
- Do not use this medicine if you are pregnant or breastfeeding.
- Do not use OxyContin 10, 20, 40 and 80 in children and adolescents under the age of 18 years.

Special warnings regarding the use of this medicine:

Do not chew, crush, dissolve, halve or break the tablet.
 Do not use this medicine if you cannot swallow the tablet whole. If you suffer from swallowing difficulties and in particular difficulties in swallowing tablets, inform your doctor before starting treatment with this medicine.

- OxyContin tablets contain oxycodone, an opioid substance, and have potential for abuse. Do not give OxyContin to another person. Take all precautions to prevent this medicine from reaching anybody other than the patient.
- Long-term use may lead to dependence!
- Do not stop taking this medicine abruptly without consulting your doctor. When discontinuing the treatment, the dosage should be reduced gradually in order to prevent withdrawal symptoms, such as: agitation, anxiety, palpitations, changes in heart rate, blood pressure and/or respiration, shaking, chills, sweating, excessive secretion (lacrimation, rhinorrhea), muscle and joint pain, eye pupil dilation, back pains, abdominal cramps, weakness, insomnia, nausea, vomiting, loss of appetite, diarrhea.
- Make sure to take OxyContin tablets according to the doctor's instructions and according to the instructions in this leaflet (see section 3, 'how to use the medicine').
- Inform your doctor about taking this medicine before any action involving anaesthesia, surgery (including dental) or an urgent treatment.
- Avoid sudden position changes from lying/sitting to standing, in order to prevent dizziness and in extreme cases fainting.
- Extra care is required in the elderly, because of their increased sensitivity to the medicine.
- If you are sensitive to any type of food or medicine, inform your doctor before starting treatment with this medicine.

Before the treatment with OxyContin tell your doctor:

- If you suffer or have suffered in the past from impaired function of the: respiratory system (e.g. asthma of any type), heart and/or the blood vessels (especially low blood pressure), liver, gallbladder, adrenal gland, kidney/urinary system, prostate gland.
- If you suffer or have suffered in the past from problems of the digestive system, e.g. esophageal or intestinal cancer, intestinal surgery, constipation or inflammatory bowel disease (IBD).
- If you suffer or have suffered in the past from convulsions, pancreatitis, underactive thyroid gland, raised intracranial pressure (can be manifested by severe headaches, among other things), mental problems due to influence of toxic substances (toxic psychosis), addiction to alcohol, medicines or drugs.
- If you have suffered in the past from withdrawal symptoms (upon stopping use of medicines or drugs), such as: restlessness, anxiety, shaking or sweating.

If you are taking or have recently taken any other medicines, including non-prescription drugs and nutrition supplements, please tell your

doctor or pharmacist. Especially inform your doctor or pharmacist if you are taking the following medicines (it should be noted that this list mentions the active ingredients of the medicines. If you are unsure whether you are using one of these medicines, please consult with your doctor or pharmacist):

- Medicines that affect the central nervous system (e.g. sedatives, hypnotics, anxiolytics, medicines for the treatment of mental disorders such as phenothiazines or neuroleptic medicines).
- Antidepressants.
- Medicines to treat high blood pressure, muscle relaxants, diuretics, medicines with an anticholinergic activity (used for example for the treatment of Parkinson's disease).
- Antifungal medications (e.g. ketoconazole, voriconazole).
- Medicines against the HIV virus (e.g. ritonavir).
- Quinidine (for the treatment of heart problems), cimidine (a medicine for the treatment of digestive problems such as stomach ulcer, heartburn).
- Carbamazepine, phenytoin (for the treatment of epilepsy).
- Antibiotics of the macrolide group (e.g. erythromycin, clarithromycin, rifampin (rifampin)).
- Medicines for general anaesthesia.
- Naltrexone and other opioid analgesics.
- Medicines of the monoamine oxidase inhibitors (MAOIs) group – see section 'Do not use the medicine if'.

Use of this medicine with food: This medicine can be taken regardless of meal times.

Use of this medicine and alcohol consumption:

Do not drink alcohol during treatment with this medicine. Drinking alcohol while using this medicine may make you feel more sleepy or increase the risk of severe side effects, such as breathing difficulties with risk of stopping breathing and loss of consciousness.

Pregnancy and breastfeeding:

Do not use this medicine if you are pregnant or breastfeeding.

Driving and use of machinery:

The use of this medicine may affect alertness, and therefore requires caution while driving a car, operating dangerous machinery, or when engaging in any other activity requiring alertness.

Use in Children: Do not use OxyContin 10, 20, 40 and 80 in children and adolescents under the age of 18 years.

3. How to use this medicine?

Always use according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure.

The dosage and administration will be determined by the doctor only.

The standard dosage is usually:

The initial dosage is usually 10 mg every 12 hours. The medicine should be administered at set intervals (usually every 12 hours), as determined by the attending doctor. Do not use this medicine more often. The doctor will adjust the appropriate dosage to treat your pain.

Do not exceed the recommended dose.

Do not change the dosage without consulting the attending doctor. If during treatment with the medicine, you continue to feel pain – refer to your doctor. Also report to the doctor if you experience events of breakthrough pain.

Do not chew, crush, dissolve, halve or break the tablet! Swallow with a glass of water, the whole tablet, otherwise the absorption may be faster which will cause severe side effects such as an overdose (see section 'If you have accidentally taken a higher dosage').

Do not retain the tablet in your mouth beyond the time necessary to swallow it.

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 in which the doctor instructed you to take a dose of more than one tablet) with a sufficient amount of water, in order to ensure complete and immediate swallowing of the tablet.

The active ingredient is gradually released from the tablet during its presence within the body and the empty tablet shell may come out in your stool (or in a bag, after a colon surgery). This is not worrisome, since the active ingredient has already been absorbed into the body.

Tests and follow up: During long-term treatment, you must undergo periodic evaluations, to evaluate the ongoing need for the medicine.

If you have accidentally taken a higher dosage or if a child or anyone else has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine. The symptoms of an overdose may include: nausea/vomiting, dizziness, constriction of the eye pupil, decrease in blood pressure, hallucinations, heavy drowsiness. Additionally, in severe cases, breathing difficulties that can cause loss of consciousness may occur. These symptoms require urgent medical assistance.

If you forget to take this medicine:

If you remember within 4 hours of the time you were supposed to take the medicine, take it immediately. Take the next dose at the regular time. If it has been more than 4 hours since you were supposed to take the medicine, consult a doctor.

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

Continue with the treatment as recommended by your doctor.

Even if your state of health improves, do not stop taking this medicine without consulting your doctor or pharmacist, and even then only gradually.

If you stop taking this medicine: Do not stop taking this medicine abruptly, unless instructed by the doctor. If you want to stop using this medicine, consult your doctor who will guide you how to do it so you do not experience withdrawal symptoms, such as: agitation, anxiety, palpitations, changes in heart rate, blood pressure and/or respiration, shaking, chills, sweating, excessive secretion (lacrimation, rhinorrhea), muscle and joint pain, eye pupil dilation, back pains, abdominal cramps, weakness, insomnia, nausea, vomiting, loss of appetite, diarrhea.

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 any further questions regarding the use of this medicine, consult your doctor or pharmacist.

4. Side effects:

Like all medicines, the use of OxyContin can cause side effects in some patients. If these side effects persist or if they are bothersome or get worse, consult your doctor. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

Refer to a doctor or a hospital emergency room immediately if the following side effects occur:

Allergic or anaphylactic reaction (manifested by breathing difficulties, swelling of the face and throat area, rash and itching upon extended areas), convulsions, respiratory depression, slow and weak breathing, confusion, memory disturbances, severe drowsiness, movement disturbances, strong abdominal pains, intestinal obstruction, decrease in blood pressure, loss of consciousness, rapid heart rate, decreased urination or urinating difficulty, dehydration, excessive sweating or chills, constricted eye pupils, hallucinations, thought disturbances.

Refer immediately to receive medical assistance if difficulties in swallowing the tablet appear, including situations in which the tablet is stuck in the throat and/or causes choking.

Common side effects (appear in more than 1 in 100 patients): constipation (the doctor can prescribe you a laxative medicine), dry mouth, digestion problems, abdominal pains or discomfort, diarrhea, nausea, vomiting, loss of appetite, anorexia, drowsiness, nervousness, depression, anxiety, tremor, headache, breathing difficulties, shortness of breath, wheezing, decreased cough reflex, dizziness, abnormal fatigue or weakness, sleeping difficulties, confusion, sweating, abnormal thoughts and dreams, itching and/or other hypersensitivity manifestations such as rash or irritation.

Uncommon side effects (appear in less than 1 in 100 patients): mood changes, feeling faint, chills, convulsions, changes in taste, agitation, hypersensitivity to pain, chest pains, decrease in blood pressure, hallucinations, fast or irregular heartbeat, dehydration, feeling of extreme happiness, decreased sexual drive, impotence, absence of menstrual periods in women, redness of the skin, flushing, thirst, edemas, enlarged lymph nodes, swelling of the hands, ankles or feet, vision disturbances, ringing in the ears, vertigo, restlessness, disorientation, reduced sensitivity to pain or touch, tingling or numbness, fever, speech difficulties, memory disturbances, spasms and changes in muscle tension, flatulence, difficulty in swallowing, hiccups, problems in the digestive system e.g. upset stomach, biliary tract disturbances (may be manifested by itchy skin, yellowing of the skin, dark urine, pale stools), inflammation of the stomach, difficulty in passing urine, retention of urine, tooth decay, reduction in size of the eye pupils, increase in liver enzymes, decrease in sodium levels, changes in ECG test (ST section), dry skin, severe peeling of the skin, urticaria, development of tolerance and dependence to the medicine, generally feeling unwell.

If at any time you experience side effects not mentioned in this leaflet or if you feel a change in your general health consult your doctor immediately!

5. How to store the medicine

Avoid poisoning! This medicine, and any other medicine, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your doctor.

When you no longer need the tablets, consult with the pharmacist about the manner of their disposal.

- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: store below 25°C.

6. Additional information

In addition to the active ingredient, the tablets also contain the following inactive ingredients:

- Polyethylene oxide, magnesium stearate, hypromellose, titanium dioxide, macrogol.

- Additionally,
 Each tablet of **OxyContin 10** contains: Hydroxypropylcellulose.

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: Hydroxypropylcellulose, indigo carmine (E132), yellow iron oxide (E172).

What does the medicine look like and what does the package contain?

OxyContin 10: white colored tablets; 20 tablets per box, in blisters.

OxyContin 20: pink colored tablets; 20 tablets per box, in blisters.

OxyContin 40: yellow colored tablets; 20 tablets per box, in blisters.

OxyContin 80: green colored tablets; 20 tablets per box, in blisters.

Registration holder: Rafa Laboratories Ltd., P.O.Box 405, Jerusalem 9100301

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

OxyContin 10: 1007128431

OxyContin 20: 1007028432

OxyContin 40: 1090129255

OxyContin 80: 1089829256

This leaflet was checked and approved by the Ministry of Health in May 2013.

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