

Patient Leaflet According to the Pharmacists' Regulations (Preparations) – 1986

This medicine is sold with a doctor's prescription only

OxyContin 5

Controlled-release tablets.

Active ingredient:

Each tablet contains: Oxycodone hydrochloride 5 mg

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

See also 'Important information about some of the medicine's ingredients' in section 2.

Read this entire leaflet carefully before using the 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 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 by 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_he.pdf

Taking this medicine along with medicines from the benzodiazepines group, other medicines which 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 that you received an explanation from your 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 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 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 high carbon dioxide level in the blood.
- You suffer from a condition where the small intestine does not work properly (intestinal obstruction, suspected intestinal obstruction, slow gastric emptying or severe abdominal pain, chronic constipation).
- You suffer from a heart problem after long-term lung disease (cor pulmonale).

- You suffer from a moderate to severe liver problem. If you suffer from other long-term liver problems, you should consult with your doctor.
- You suffer from a severe impairment in the kidney function.
- You have intolerance to some sugars since the tablet contains lactose.

Special warnings regarding the use of this medicine:

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

- You suffer or have suffered in the past from opioid, alcohol, medicine or drug dependence and/or addiction.
- 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 or drugs.
- You feel you need to take more tablets to get the same measure of pain relief. This phenomenon may be a sign that you are developing tolerance to the medicine or are becoming addicted to it. In this case contact your doctor in order to evaluate whether a change in dosage or replacement of the medicine with another pain reliever is necessary.
- You suffer from mental problems such as depression.
- You are elderly or weakened.
- You suffer from an underactive thyroid gland (hypothyroidism), as you may need a lower dose; or from another problem of the thyroid gland (myxedema) that is manifested in dryness, cold and swollen skin and affects the face and limbs.
- You suffer from a head injury, brain tumor or injury, increased pressure in the skull (that can be manifested 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 experience a feeling of dizziness and faintness or reduction in consciousness level .
- You suffer from a mental problem as a result of an infection (toxic psychosis).
- 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 Addison's disease.
- You suffer from breathing problems such as severe lung disease. The symptoms can include breathlessness and coughing.
- You suffer from a condition in which your breathing stops for a short time when you are sleeping, a condition called sleep apnea.
- You suffer from kidney or liver problems.
- You suffer or have suffered in the past from problems in the digestive system (such as constipation, intestinal surgery).

Additional warnings:

- OxyContin tablets contain oxycodone, an opioid substance, and have a potential for drug 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. 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, nervousness, 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 your 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. Excessive use and abuse may lead to an overdose and even to 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.
- The medicine may cause and/or worsen breathing problems while sleeping, e.g. pauses in breathing while asleep. If you feel these symptoms or someone else in your surroundings observes these symptoms in you contact your doctor. The doctor may recommend reducing the dosage.
- If you are due to undergo an operation or any other procedure involving anesthesia, please tell the doctor that you are taking this medicine. Its 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.
- Avoid a sudden change from a prone/sitting position to a standing position, in order to avoid dizziness and in extreme cases fainting.
- You may experience hormonal changes during the period of treatment with the medicine.

Children and adolescents:

The efficacy and safety of the medicine has not been tested in children under the age of 18 years. The medicine is not intended for children under the age of 6 years .

You should consult the doctor regarding the use of OxyContin 5 in children and adolescents aged between 6 and 18 years.

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.
- Your doctor may monitor possible hormonal changes.

Drug interactions:

- **Taking opioids concomitantly with sedatives (medicines that cause sedation, calmness or sleep induction) such as benzodiazepines or similar medicines** increases the risk of drowsiness, breathing difficulties (respiratory depression) and coma and might be life-threatening. Therefore, concomitant use should be considered only if there are no other treatment options available. If your doctor has decided to prescribe sedatives for you together with OxyContin, the doctor may limit the dosage and duration of the concomitant treatment.
- **The risk of side effects increases, if you take antidepressants** (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine) **or other serotonergic medications.** These medicines may interact with OxyContin and cause you to experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye; agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C (serotonin syndrome). Contact the doctor if you experience these symptoms.

Please strictly follow your doctor's recommendation regarding the dosage. It is recommended to ask friends and relatives to pay attention to the symptoms mentioned above. 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 your doctor or pharmacist. Especially inform your doctor or pharmacist if you are taking the following medicines (it should be noted that

the following list indicates the active ingredients in the medicines. If you are not sure whether you are using one of these medicines please consult with your doctor or pharmacist):

- Medicines of the monoamine oxidase inhibitors group (MAOIs) - also tell your doctor if you have taken this medicine during the last two weeks. Concomitant treatment with these medicines is not recommended.
- Medicines which affect the central nervous system such as: sedatives and sleep-inducing medicines including benzodiazepines, anti-anxiety medicines, medicines for the treatment of mental disorders (e.g. phenothiazines, neuroleptic medicines), anesthetics.
- Antidepressants such as paroxetine (see also warning above), other strong medicines for the relief of pain (such as other opioid pain relievers).
- Muscle relaxants, medicines for the treatment of high blood pressure.
- Quinidine (for the treatment of heart problems), cimetidine (a medicine for the treatment of digestive problems such as stomach ulcer, heartburn).
- Antifungals (such as ketoconazole, voriconazole, itraconazole, posaconazole).
- Antibiotics from the macrolide group (such as: clarithromycin, erythromycin, telithromycin); rifampicin (for treatment of tuberculosis).
- Medicines against the HIV virus from the protease inhibitors group (such as boceprevir, ritonavir, indinavir, nelfinavir, saquinavir).
- Carbamazepine (for the treatment of epilepsy, convulsions and certain types of pain); phenytoin (for the treatment of epilepsy, convulsions).
- Antihistamines.
- The Hypericum plant (also known as St. John's Wort).
- Anticholinergics or medicines with an anticholinergic activity, certain medicines for the treatment of Parkinson's disease.
- Gabapentinoids such as Pregabalin.

Use of this medicine and food:

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

Use of the 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 the 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 your 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 the birth, which may need to be treated. The symptoms may include: restlessness, hyperactivity, abnormal sleeping patterns, high-pitched crying, tremor, vomiting, diarrhea, lack of weight gain.
- **Childbirth:** 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 substance (oxycodone) passes into breastmilk and can affect the baby (it may cause respiratory depression in the baby).

Driving and use of machinery: The use of this medicine may cause a number of 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 treatment and/or with a dosage increase. If you feel these effects and/or any other effect which might affect the driving ability, do not drive or operate machinery. Do not drive until you know how the medicine affects you. As for children, they should be warned against riding a bicycle or playing near roads, etc.

Important information about some of the medicine's ingredients:

- Each tablet contains approximately 77 mg lactose (a type of sugar). If you have intolerance to certain sugars, inform your doctor before taking this medicine (see section 6).
- The tablets contain the brilliant blue coloring agent (E133) which might cause an allergic reaction.

3. How to use this medicine?

Always use according to the doctor's instructions. Check with your 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 your prescribing doctor discussed with you the duration of the treatment with the medicine, a plan for discontinuing the treatment and how to gradually stop taking the medicine.

The standard dosage is usually:

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

Do not change the dosage without consulting with the attending doctor. If during treatment with the medicine you continue to experience pain, contact the doctor. In addition, inform your attending doctor if you experience episodes of breakthrough pain.

Patients with kidney or liver problems: Tell your 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 dosage.

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 might be life-threatening (see section 'if you accidentally took a higher dosage').

Do not crush and inject the tablets since this may lead to serious side effects and even death.

The active substance is released gradually from the tablet during the time that it is in your body and the tablet's empty matrix may be expelled in your stools (or in the bag, after colon surgery). This phenomenon is not a case for concern, since the active substance 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 to a hospital emergency room and bring the medicine package . Symptoms of an overdose may cause extreme drowsiness, nausea/vomiting, dizziness, decrease in muscle tone, hallucinations, constricted pupils, slow heartbeat (bradycardia), decrease in blood pressure. Pulmonary edema, breathing difficulties (up to respiratory depression) may also appear, which may cause a loss of consciousness and even death. Overdose symptoms require urgent medical care in a hospital.

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 with your doctor.

Do not take a double dose to make up for a forgotten dose!

Adhere to the treatment as recommended by your doctor.

Even if your state of health improves, do not stop the treatment with the medicine without consulting your 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, consult your doctor who will guide you how to do this. Your doctor will usually recommend that you gradually reduce the dosage in order to reduce the risk of the appearance of withdrawal symptoms such as: restlessness, sleeping difficulties, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increase in blood pressure, nausea, vomiting, diarrhea, increased heart and/or breathing rate, loss of appetite, shaking, shivering, sweating, tearing, runny nose, yawning, muscle pain, dilated pupils, abdominal cramps, weakness.

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 your doctor or pharmacist.

4. Side effects

Like 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 an allergic reaction can include sudden wheezing, breathing difficulties, , swelling in the face, eyelids or lips, rash and/or itching (particularly in large areas of the body).
- **Respiratory depression.** This side effect is extremely serious and is manifested in breathing that is slower and weaker than normal.
- **Withdrawal symptoms:** when you stop taking the medicine, you may experience withdrawal symptoms. See section 'If you stop taking the medicine'.

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 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 start feeling well again when you take the medicine anew. If you experience these symptoms refer to your 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 cough reflex; rash, sweating (including excess sweating).

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

A need to take increasingly higher doses of the medicine to obtain the same level of pain relief (tolerance to the medicine), withdrawal symptoms, difficulty swallowing, belching, hiccups, wind, intestinal blockage (ileus), inflammation of the stomach, changes in taste; vertigo (feeling of dizziness or spinning), hallucinations, mood changes, despondency, feeling of extreme happiness (euphoria), restlessness, agitation, generally feeling unwell, loss of memory, disorientation, difficulty speaking, reduced sensitivity to pain or touch, tingling or numbness, seizures, convulsions, visual disturbances such as blurred vision, fainting, unusually rigid or lax muscles, involuntary muscle contractions; difficulty 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, feeling your heartbeat, dilation of blood vessels, skin redness; dehydration, thirst, chills, swelling of hands, ankles or feet, edema; dry skin, severe flaking or peeling of the skin; redness of the face (flushing), decrease in eye pupils size, muscle spasm, fever; colicky abdominal pain and/or abdominal 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):

Urticaria (hives), low blood pressure, feeling of fainting (especially upon standing up).

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

Development of dependency and addiction, hypersensitivity to pain, aggression, tooth decay, lack of menstrual period in women, obstruction of bile flow from the liver (may be manifested in itchy skin, yellowing of the skin, dark urine, pale stools); sleep apnea (a condition where your breathing stops for a short time while you are asleep); withdrawal symptoms in the newborn (see section 'Pregnancy and breastfeeding').

If a side effect appears, if any of the side effects worsens, 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) which 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. 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.

6. Additional information

- **In addition to the active ingredient, the tablets also contain:**

Lactose, stearyl alcohol, ammonio methacrylate copolymer, povidone, hypromellose, talc, glyceryl triacetate, magnesium stearate, titanium dioxide, macrogol 400, brilliant blue (E133).

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

Round light blue tablets packed in blisters in packages of 20 tablets.

Manufacturer: Napp Pharmaceuticals, England.

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

Medicine registration number in the National Medicines Registry of the Ministry of Health:
1317530830

Revised in February 2021 in accordance with the Ministry of Health guidelines.

N-276006