

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

The medicine is dispensed with a doctor's prescription only

## Oxycod Forte 10 mg/ml Syrup

### Active ingredient:

Each 1 milliliter (ml) contains: oxycodone hydrochloride 10 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 the entire leaflet carefully before using the medicine.

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

This medicine has been prescribed for treatment of your condition. 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 18 years of age.

Medicines from the opioid group may cause addiction, especially with prolonged use, and have the potential for abuse and overdose. A reaction to an overdose can be manifested by slow breathing and even cause death. Make sure you know the name of the medicine, the dosage you are taking, the frequency of administration, the duration of treatment, potential side effects and risks. Additional information regarding the risk of dependence and addiction can be found at the 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 with medicines of the benzodiazepine group, with other medicines that depress the central nervous system (including drugs) or with 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 moderate to severe pain.

### Therapeutic group: opioid analgesics.

The medicine has been prescribed for you only and should not be passed to anyone else. Opioids may cause addiction and you may experience withdrawal symptoms if you stop taking them suddenly. Make sure you receive an explanation from the doctor on the duration of treatment with the medicine, and when it is appropriate to stop taking it, 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 syrup contains (for a list of the additional ingredients, see section 6).
- You suffer from breathing problems, such as: severe chronic obstructive lung disease, severe bronchial asthma, severe respiratory depression. The symptoms may include shortness of breath, cough or breathing more slowly or weakly than expected.
- You suffer from a condition in which the small bowel does not function properly (intestinal obstruction), slow gastric emptying, severe abdominal pain, chronic constipation.
- You suffer from a heart problem after a prolonged lung disease (cor pulmonale).
- You suffer from a high carbon dioxide level in the 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, consult the doctor.
- You are under the age of 18.

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

#### Before (and during) treatment with Oxycod Forte Syrup tell the doctor if:

- You or anyone in your family suffers or has ever suffered from addiction to opioids, alcohol, medicines or drugs.
- You smoke.
- You have ever had problems with your mood (depression, anxiety, personality disorder) or if you have previously suffered from other mental problems treated by a psychiatrist.
- You have previously suffered from withdrawal symptoms, such as: agitation, anxiety, shaking or sweating due to discontinuing use of alcohol, medicines or drugs.
- You feel you need to take more of the medicine to obtain the same degree of pain relief. This effect can be a sign that you are developing tolerance to the effects of the medicine or becoming addicted to it. In this case, refer to the doctor to evaluate whether it is necessary to change the dosage or replace the medicine with another pain reliever.
- 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 thyroid problem manifested by dry, cold, swollen and puffy skin affecting the face and limbs.
- You suffer from a brain injury or tumor, a head injury, increased intracranial pressure (which can be manifested by 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, experience a fainting sensation or a decreased level of consciousness.
- You suffer from a mental problem as a result of using certain medicines (toxic psychosis), alcoholism or delirium tremens (psychosis caused by alcohol withdrawal).
- You suffer from inflammation of the pancreas (which causes severe pain in the abdomen and back); problems with the gallbladder or biliary tract; inflammatory bowel disease; enlargement of the prostate gland, causing difficulty in passing urine (in men); impaired function of the adrenal gland such as Addison's disease (may cause symptoms such as weakness, weight loss, dizziness, nausea, vomiting).
- You suffer from a severe impairment in lung function. The symptoms may include shortness of breath and cough.
- You suffer from prolonged pain unrelated to cancer.
- You suffer from a condition in which your breathing stops for a short time while you are asleep, a condition called sleep apnea.
- You suffer from kidney or liver problems.

#### Tolerance, dependence and addiction

- The syrup contains oxycodone (an opioid component), which has a potential for abuse.** Do not give the syrup to someone else. Take all precautions to prevent the medicine from reaching anyone who is not the patient.
- Prolonged use may lead to dependence.**
- Recurrent or frequent use of opioids may reduce the effectiveness of the medicine, due to developing tolerance and becoming accustomed to the medicine.
- Taking this medicine regularly, particularly for a long time period, may cause dependence, addiction and abuse. This may cause a life-threatening overdose. If you are concerned that you may develop dependence on the medicine, it is important to consult your doctor. Make sure you receive an explanation from the doctor on the duration of treatment with the medicine, and when it is appropriate to stop taking it, how to do so safely.
- Dependence or addiction may cause a feeling of having no control over the quantity of the medicine taken and how often it is taken. You may feel a need to take the medicine for a longer time period, or a need to increase the dosage regardless of the relief in pain intensity.
- The risk of developing dependence or addiction varies from one person to another. You may be at a greater risk of developing dependence and addiction if:
  - You or someone in your family has previously abused or developed dependence on alcohol, medicines or drugs.
  - You smoke.
  - You have previously had problems with your mental state (depression, anxiety, personality disorders), or if you have been treated by a psychiatrist for other mental problems.
- Addiction can cause withdrawal symptoms when you stop taking the medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling the heart beats (palpitations), increase in blood pressure, nausea, vomiting, diarrhea, loss of appetite, shaking, chills, sweating. If you notice one of these signs, it is important to consult the doctor to discuss the right treatment options for you, including receiving instructions on when and how to stop the treatment by gradually reducing the dosage. It is important not to stop taking the medicine suddenly, as this increases the risk of experiencing withdrawal symptoms. 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 can lead to an overdose and even to death.
- In rare cases, increasing the dosage of the medicine may make you more sensitive to pain. In this case, consult the doctor regarding the treatment.

#### Additional warnings:

- Sleep-related breathing problems:** the medicine can cause sleep-related breathing problems, such as sleep apnea (breathing pauses during sleep), and sleep-related hypoxemia (low oxygen level in the blood). Tell the doctor if you or anyone around

you notices the following symptoms: breathing pauses during sleep, waking up due to shortness of breath, difficulty staying asleep, increased drowsiness during the day. In this case, the doctor may recommend reducing the dosage.

- Do not inject the solution. Injecting the solution may cause serious side effects including tissue death at the injection site, infection, inflammation of the lungs and damage to the heart which may cause death.
- If you have recently had or if you are about to have an operation (including dental) or any procedure involving anesthesia, tell the doctor that you are taking this medicine, as it may be necessary to adjust the dosage. It should be used with extreme caution for up to 24 hours after the surgery and according to the doctor's instructions.
- You may experience hormonal changes during the treatment with the medicine.
- Avoid sudden changes from a lying/sitting position to standing, to avoid dizziness and, in extreme cases, fainting.
- Refer to the doctor if you suffer from severe upper abdominal pain possibly radiating to the back, or from nausea, vomiting and fever, as these symptoms can indicate inflammation of the pancreas or biliary tract.

### Children and adolescents:

- This medicine is not intended for children and adolescents under 18 years of age.
- If necessary and according to the doctor's instructions, the medicine Oxycod Syrup, which is less concentrated (the concentration of Oxycod Syrup is 2 mg in each 1 ml) and intended for children from the age of 6 years, can be used.

### Tests and follow-up:

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

### Drug interactions:

**Taking Oxycod Forte Syrup together with other medicines that depress the central nervous system** may cause slow breathing or breathing difficulties (respiratory depression), severe sleepiness, loss of consciousness/coma and death. For this reason, the doctor will consider using Oxycod Forte Syrup together with these medicines only if there are no other treatment options available, and only at a low dosage and for short periods. 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; sedative medicines, sleep-inducing medicines (such as benzodiazepines); medicines for treatment of mental/psychiatric problems (such as phenothiazines); antidepressants, anesthetics; muscle relaxants; medicines for the treatment of high blood pressure; medicines from the monoamine oxidase inhibitors (MAOIs) group, used, for instance, for the treatment of depression, such as tranylcypromine, phenelzine, isocarboxazid. Do not use Oxycod Forte Syrup if you are taking, or have taken in the last two weeks, medicines from the MAOIs group.

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

**Taking Oxycod Forte Syrup with medicines used for the treatment of depression from the SSRIs or SNRIs group (selective serotonin/norepinephrine reuptake inhibitors) or with other serotonergic medicines may cause serotonin toxicity.** The symptoms include: changes in the mental condition such as agitation, seeing or hearing non-existing things (hallucinations), loss of consciousness/coma; a fast heartbeat, blood pressure changes, increased body temperature, muscle twitching, lack of coordination, heightened reflexes, stiffness; gastrointestinal 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.

**If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist.** The doctor may adjust the dosage of the medicines. Especially inform the doctor or the pharmacist if you are taking the following medicines:

- Certain antidepressants from the tricyclic antidepressants group, such as: amitriptyline, clomipramine, imipramine, lofepramine, nortriptyline.
- Medicines used for treatment of allergies (antihistamines), such as: cetirizine, fexofenadine, chlorphenamine.
- Medicines for the treatment of Parkinson's disease.
- Antibiotics of the macrolide group, such as: clarithromycin, erythromycin, telithromycin.
- Antifungals, such as: ketoconazole, voriconazole, itraconazole, posaconazole.
- Anti-HIV medicines from the protease inhibitor group, such as: boceprevir, ritonavir, indinavir, nelfinavir, saquinavir.
- Cimetidine (for the treatment of stomach ulcer).
- Rifampicin (for the treatment of tuberculosis).
- Medicines for treatment of convulsions/seizures, such as: carbamazepine and phenytoin.
- The Hypericum plant (also called St. John's wort), used for the treatment of depression.
- Quinidine (for treatment of irregular heartbeat).
- Medicines with anticholinergic activity.

### Use of the medicine and food:

The medicine may be taken regardless of meal times.

Avoid grapefruit consumption during treatment with the medicine.

### Use of the medicine and alcohol consumption:

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

Drinking alcohol during the period of treatment with the medicine may make you feel sleepy or increase the risk of serious side effects, such as shallow breathing with a risk of stopping breathing and losing consciousness.

### Pregnancy and breastfeeding:

- Pregnancy:** do not use this medicine if you are pregnant, if you think you are pregnant or if you are planning to become pregnant, unless the doctor has decided that the benefit of using the medicine outweighs the potential 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: irritability, hyperactivity, abnormal sleep patterns, high pitched crying, shaking, vomiting, diarrhea, not putting on weight.
- Labor:** the use is not recommended during labor. Use during labor may cause respiratory depression in the newborn.
- Breastfeeding:** do not use the medicine during the breastfeeding period, as the active ingredient (oxycodone) passes into breastmilk and may affect the baby (may cause respiratory depression in the baby).

### Driving and use of machinery:

The use of this medicine may cause several side effects that may adversely affect your ability to drive or operate machinery (e.g., drowsiness, dizziness). See section 4 for the full list of side effects. Usually, these side effects are felt more at the beginning of treatment and/or when the dosage is increased. If you feel these effects, and/or any other effect that 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 as to whether driving is safe for you during the treatment period, consult the doctor.

### Important information about some of the medicine's ingredients:

- Each 1 ml of syrup contains 2.5 mg sodium saccharine.
- Each 1 ml of syrup contains 1 mg sodium benzoate. Sodium benzoate may increase the risk of jaundice (yellowing of the skin and eyes) in newborn babies (up to the age of 4 weeks).
- The syrup contains the coloring substance sunset yellow, which may cause an allergic reaction such as asthma. This effect is more common in patients with an allergy to aspirin.
- Each 1 ml contains less than 5.5 mg sodium.

### 3. How to use the medicine?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen with the medicine.

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

Before starting treatment and during treatment, the doctor will inform you what to expect from the treatment, the duration of treatment with the medicine, in which cases you should refer to a doctor and when you should stop treatment according to a plan of gradually stopping to take the medicine (additional information in subsection "If you stop taking the medicine").

The doctor will adjust your dosage according to your condition and the intensity of your pain. This medicine should be used at set intervals as determined by the attending doctor.

Do not change the dosage without consulting the attending doctor. If you continue to feel pain during treatment with the medicine – refer to the doctor.

**Patients with kidney or liver problems:** inform 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.

#### Method of use:

The syrup is intended for oral administration only. See also "Additional warnings" in section 2. Be sure to measure the dose precisely using the enclosed syringe.

The dose can be mixed with a little soft drink to improve the taste.

Do not drink the solution directly from the bottle, as this increases the risk of an overdose.

**If you accidentally took a higher dosage** or if a child or any other person accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room and bring the medicine package with you. An overdose may make you very sleepy and also cause symptoms such as: nausea/vomiting, dizziness, hallucinations, decrease in blood pressure, constriction of pupils, decrease in muscle tone (hypotonia), bradycardia (slow heart rate). Additionally, pulmonary edema, breathing difficulties (up to respiratory depression) or cardiovascular collapse may also appear, which can cause loss of consciousness, coma and even death. An overdose may even cause a brain disorder (toxic leukoencephalopathy). These symptoms require urgent medical assistance in a hospital. It is advisable to ask those around you to also be familiar with these symptoms and notice if you develop them.

### If you forgot to take the medicine:

If you forgot to take this medicine at the appointed time, take a dose as soon as you remember, but make sure to have an interval of at least four hours between doses. Do not take a double dose to compensate for the forgotten dose.

Adhere to the treatment as recommended by the doctor.

Even if there is an improvement in your health condition, do not stop treatment with the medicine without consulting the doctor, and even then, usually only gradually.

### If you stop taking the medicine:

Do not stop taking the medicine suddenly. If you want to stop taking the medicine, consult a doctor first, who will instruct you on how to do so. The doctor will usually advise you to reduce the dosage gradually in order to reduce the risk of withdrawal symptoms, such as: agitation/restlessness, sleeping difficulties, irritability, anxiety, feeling of heart beats (palpitations), increased blood pressure, nausea, vomiting, diarrhea, shaking, shivering, sweating, tearing, runny nose, yawning, muscle aches, dilated pupils, excessive movements, weakness, abdominal cramps, loss of appetite, increased heart and/or breathing rate.

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

### If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

### 4. Side effects

As with any medicine, using Oxycod Forte Syrup 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.

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

- An 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 wheeziness, breathing difficulties, swelling of the face, eyelids or lips; rash and/or itching (especially in widespread body areas).
- Respiratory depression:** the most serious side effect is a condition where you breathe more slowly or weakly than usual, which may 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 in combination with certain other medicines (see also "Drug interactions" in section 2). It is recommended to ask those around you (friends, family, caregivers) to notice if 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.

### 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 of time than the doctor recommended and/or take a higher dose than the one the doctor recommended; using 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 feel these symptoms, refer to the doctor.

### Additional side effects:

*Very common side effects (occur in more than one user out of ten):*

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

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

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

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

Difficulty in swallowing, belching, hiccups, wind, abnormal bowel activity (intestinal blockage, ileus), inflammation of the stomach, changes in taste or unpleasant taste; vertigo (dizziness or a feeling of spinning), hallucinations, mood changes, depression, feeling of extreme happiness (euphoria), disorientation, restlessness, agitation, generally feeling unwell, loss of memory, difficulty in speaking, reduced sensitivity to pain or touch, tingling or numbness, seizures, convulsions, blurred vision or impaired vision, fainting, unusual muscle stiffness or slackness, involuntary muscle contractions, muscle spasms; pain or difficulty in passing urine (including urinary retention), impotence, decreased sexual drive, low level of sex hormones as seen in blood tests (hypogonadism); fast and/or irregular heartbeats (palpitations), dizziness, dilation of blood vessels, skin redness; dehydration, thirst, chills, swelling of the hands, ankles or feet, edema; dry skin, severe peeling or flaking of the skin; redness of the face (flushing), reduction in the size of the eye pupils, fever; spasmodic abdominal pain and/or abdominal discomfort (which can be due to bile problems); worsening of liver functions (seen in blood tests, for example: increased liver enzymes).

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

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

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

Dependence and addiction (see above – "How to identify a state of addiction"); withdrawal symptoms (see "Tolerance, dependence and addiction" in section 2); a need to take increasingly higher doses of the medicine to obtain the same level of pain relief (tolerance to the medicine); increased sensitivity to pain, aggression, tooth decay, absence of menstrual periods in women, a dysfunction of the "Oddi" sphincter (a valve in the gastrointestinal system), which may cause severe upper abdominal pain (sphincter of Oddi dysfunction), a blockage in the flow of bile from the liver (can be manifested by itchy skin, yellowing of the skin, dark urine, pale stools); sleep apnea (breathing pauses during sleep); withdrawal symptoms which may be life-threatening in babies born to mothers who took the medicine for a prolonged period during pregnancy (see also section 2 "Pregnancy and breastfeeding").

### 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.

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage ([www.health.gov.il](http://www.health.gov.il)), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il/>

### 5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept 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 or by anyone else to whom the medicine is not intended, is dangerous and may cause death. Do not induce vomiting without an explicit instruction from the doctor.
- When you no longer need the medicine, consult the pharmacist on how to dispose of it.
- 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.
- After opening for the first time, the syrup can be used for 3 months, but no later than the expiry date stated on the package.

### 6. Additional information

#### In addition to the active ingredient, the syrup also contains:

Citric acid, saccharin sodium, tri-sodium citrate, sodium benzoate, sunset yellow (E110), hydrochloric acid, sodium hydroxide, purified water.

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

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

A brown glass bottle with a child-resistant cap, containing 30 ml of a clear, orange solution. A syringe to measure the dose to be taken orally is enclosed with each package.

#### 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:** 1476433521

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