

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

The medicine is dispensed with a doctor's prescription only

Targin 5, Targin 10, Targin 20, Targin 30, Targin 40

Prolonged-release tablets

Active ingredients:

Medicine	Oxycodone hydrochloride	Naloxone hydrochloride (as dihydrate)
Targin 5	5 mg	2.5 mg
Targin 10	10 mg	5 mg
Targin 20	20 mg	10 mg
Targin 30	30 mg	15 mg
Targin 40	40 mg	20 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 you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

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

Taking this medicine with medicines of the benzodiazepine group, with 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?

Targin is intended for the relief of moderate to severe pain. **Targin** contains two active ingredients, oxycodone and naloxone. The oxycodone is intended for the relief of moderate to severe pain, in adults who need an opioid pain reliever around the clock, for a few days or more. The naloxone is added to reduce the constipation caused by the activity of the opioid oxycodone in the digestive system.

Therapeutic group: oxycodone – opioid analgesic, naloxone – opioid antagonist.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredients or to any of the additional ingredients the tablets contain (for the list of the additional ingredients, see section 6).
- You suffer from respiratory depression (your breathing cannot supply enough oxygen to the blood and eliminate carbon dioxide); severe lung disease associated with narrowing of the airways (COPD); severe bronchial asthma.
- You suffer from cor pulmonale (a condition in which the right side of the heart is enlarged due to increased pressure in the blood vessels in the lung, for instance).
- You suffer from intestinal obstruction that is not caused by opioid use.
- You suffer from moderate to severe liver function impairment.

Special warnings regarding the use of the medicine:

Before treatment with Targin, tell the doctor if:

- You or someone in your family is addicted or has ever been addicted to opioids, to alcohol, to prescription medicines or to drugs (abuse or dependence).
- You are an elderly or debilitated (weak) patient.
- You suffer from: intestinal obstruction caused by the use of opioids; impaired kidney function; impaired liver function; severely impaired lung function (reduced breathing ability); frequent breathing pauses during sleep, which may make you feel very sleepy during the day (sleep apnea); myxedema – thyroid gland function disorder accompanied by dryness, coldness and swelling of the skin of the face or the limbs.
- Your thyroid gland does not produce enough hormones (underactive thyroid gland or hypothyroidism).
- Your adrenal glands do not produce enough hormones (adrenal insufficiency, Addison's disease).
- You suffer from a mental illness accompanied by a (partial) loss of reality (psychoses), as a result of alcohol or of the toxic effect of other substances (substance-induced psychosis).
- You suffer or have ever suffered from problems with your mood (depression, anxiety or personality disorder) or you are being treated or have been treated by a psychiatrist in relation to other mental illnesses.
- You suffer from gallstone problems.
- You suffer from an enlarged prostate gland (prostate hypertrophy).
- You suffer from alcoholism or delirium tremens (a psychosis caused by alcohol withdrawal).
- You suffer from an inflammation of the pancreas.
- You suffer from low blood pressure or high blood pressure.
- You have a pre-existing cardiovascular disease.
- You smoke.
- You suffer from a head injury (due to the risk of increased intracranial pressure).
- You suffer from epilepsy or are prone to convulsions/seizures.
- You are taking a medicine from the monoamine oxidase inhibitors (MAOIs) group (used for treatment of depression or Parkinson's disease), or you have taken this type of medicine within the last two weeks, such as medicines containing tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid.
- You suffer from sleepiness or episodes of suddenly falling asleep.
- You suffer from any biliary tract problem (diseases that affect the bile ducts, gallbladder, etc.).

Repeated use of **Targin** may cause dependence and abuse, which may lead to a life-threatening overdose. If you are concerned that you will develop dependence on **Targin**, it is important to consult the doctor.

Sleep-related breathing disorders

The medicine may cause sleep-related breathing disorders, such as sleep apnea (breathing pauses during sleep) and hypoxemia (low oxygen level in the blood). The symptoms may include breathing pauses during sleep, night awakening due to shortness of breath, difficulty sleeping continuously or increased drowsiness during the day. If you or someone around you notices that you have these symptoms, refer to the doctor. The doctor may consider reducing the dosage.

Tell the doctor if you have previously suffered from the above-mentioned conditions, and also if they develop during treatment with the medicine. The most serious result of an opioid overdose is respiratory depression (slow and shallow breathing). This may also cause a decrease in blood oxygen level, leading to fainting, etc.

Additional warnings:

- Swallow the prolonged-release tablet whole, so as not to harm the slow release mechanism of oxycodone hydrochloride from the tablet. Do not break, chew, crush or halve the tablet! Taking non-intact tablets may lead to the absorption of a life-threatening dose of oxycodone hydrochloride (see "If you accidentally took a higher dosage", in section 3).
- If you have severe diarrhea at the start of treatment, this may be the effect of the naloxone. It may be a sign that the bowel is returning to normal function. Such diarrhea may occur within the first 3 to 5 days of treatment. If the diarrhea persists for longer than 3-5 days, or if it is bothersome, refer to the doctor.
- If you have used another opioid before treatment with **Targin**, there may be withdrawal symptoms upon switching to **Targin**, such as: restlessness, bouts of sweating and muscle pain. If you experience such withdrawal symptoms, you may need closer medical monitoring.

Tolerance, dependence and addiction

This medicine contains oxycodone, which is an opioid. It may cause dependence and/or addiction.

This medicine contains the active ingredient oxycodone hydrochloride, which is an opioid pain reliever. Repeated use of opioid pain relievers may result in the medicine being less effective (you become used to it, an effect known as tolerance). Repeated use of **Targin** may also cause dependence, abuse and addiction, which may lead to a life-threatening overdose. The risk of these side effects can increase with a higher dosage and a longer duration of use. The doctor who prescribed you the medicine should explain for how long you should take it, and when it is appropriate to stop, how to do so safely.

Dependence or addiction may make you feel that you have no control of the amount of medicine you need or how often you take it. You may feel that you need to continue taking the medicine, even when it does not help relieve your pain. The risk of developing dependence or addiction varies from one person to another. You may be at an increased risk of dependence on or addiction to **Targin** if:

- You or someone in your family is addicted or has ever been addicted to alcohol, to prescription medicines or to drugs (abuse or dependence).
- You smoke.
- You suffer or have ever suffered from problems with your mood (depression, anxiety or personality disorder) or you are being treated or have previously been treated by a psychiatrist in relation to other mental illnesses.

If you notice any of the following signs during treatment with **Targin**, you may have become addicted to or developed a dependence on the medicine:

- You need to take the medicine for longer than advised by the doctor.
- You need to take more than the recommended dose.
- You are using the medicine for reasons other than that for which it was prescribed for you, for example, "to stay calm" or "to help you sleep".
- You have made repeated, unsuccessful attempts to stop taking the medicine or control its use.
- You feel unwell when you stop using the medicine and feel better once you take it again ("withdrawal symptoms").

If you notice any of these signs, talk to the doctor about the best manner of treatment for you, including when it is appropriate to stop the treatment and how to do so safely (see "If you stop taking the medicine" in section 3).

- Contact your doctor if you experience severe upper abdominal pain which may radiate to the back, nausea, vomiting or fever, as these may be symptoms associated with inflammation of the pancreas or of the biliary tract system.
- Tell the doctor if you have cancer associated with peritoneal metastases or in case of a beginning of intestinal obstruction in advanced stages of digestive system or pelvic cancer.
- If you are about to undergo surgery or have just had surgery, tell the doctor at the hospital that you are taking these tablets. The doctor may need to adjust your treatment. Do not use this medicine for treatment of short-term pain after the surgery, due to the increased risk of dependence and shortness of breath.
- Similar to other opioids, oxycodone may affect the natural production of hormones in the body, for example cortisol or sex hormones, especially when taking high doses for long periods. If you experience persistent symptoms such as nausea or vomiting, loss of appetite, tiredness, weakness, dizziness, menstrual cycle changes, impotence, infertility or decreased sexual drive, consult with the doctor. Your hormone levels may need to be monitored.
- The medicine may increase your sensitivity to pain, especially at a high dosage. Tell the doctor if this happens. It may be necessary to reduce the dosage or change the medicinal treatment.
- You may notice the remains of the tablet in your stool. Don't worry, since the active ingredients in the tablet have already been released in the digestive system and absorbed into your body.

Incorrect use of Targin:

- Targin** is not suitable for treatment of withdrawal symptoms. You should never abuse **Targin**, especially if you have a drug addiction. If you are addicted to substances such as heroin, morphine or methadone, there may be severe withdrawal symptoms if you abuse the tablets, since they contain naloxone. If you already suffer from withdrawal symptoms, they may worsen.
- You should never misuse the tablets by dissolving the tablets and injecting them (for example, into a blood vessel). Especially as they contain talc, which may cause local tissue destruction (necrosis) and changes in the lung tissue (pulmonary granuloma). Such abuse may lead to other serious consequences and even death.
- The use of **Targin** can produce a positive result in a test for drugs/prohibited substances for athletes.
- The use of **Targin** to improve athletic performance poses a health hazard.

Children and adolescents: there is no information regarding the safety and effectiveness of use in children and adolescents under the age of 18 years; therefore, the use is not recommended.

Tests and follow-up: during long-term treatment, you should undergo periodic evaluations in order to evaluate the ongoing need for the medicine.

Drug interactions:

- The risk of side effects increases if you are taking antidepressants** (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine). These medicines may interact with oxycodone and you may feel symptoms such as involuntary, rhythmic muscle contractions, including the muscles that control eye movement, agitation, hallucinations, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C, coma, tachycardia (fast heartbeat), blood pressure changes, lack of coordination, muscle stiffness, gastrointestinal symptoms (nausea, vomiting, diarrhea). Refer to the doctor if you feel these symptoms.
- Using opioids concomitantly with sedative medicines (those that cause sedation, calm or induce sleep) such as benzodiazepines or similar medicines** increases the risk of drowsiness, breathing difficulties (respiratory depression) and coma and may be life-threatening. Therefore, concomitant use should only be considered when there are no other treatment options. However, if your doctor has decided to prescribe you sedative medicines together with **Targin**, he will need to limit the dosage and the duration of the combined treatment. Tell the doctor about all the sedative medicines you are taking. Examples of such or related medicines include: other strong pain relievers (opioids); medicines for treatment of epilepsy, pain and anxiety, such as gabapentin and pregabalin; sleep-inducing and calming medicines (including benzodiazepines, hypnotic and anti-anxiety medicines); antidepressants; medicines for treatment of allergy, motion sickness or nausea (antihistamines or antiemetics); medicines for treatment of psychiatric or mental problems (antipsychotic medicines including phenothiazines and neuroleptic medicines); muscle relaxants; medicines for treatment of Parkinson's disease.

Please follow the doctor's dosage recommendations closely. It is advisable to ask friends and relatives to pay attention to the symptoms mentioned above. Refer to the doctor if you feel these symptoms.

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Especially if you are taking:

- Anticoagulants (such as coumarin derivatives);
- Antibiotics from the macrolide group (such as clarithromycin, erythromycin, telithromycin);
- Antifungals from the azole group (such as ketoconazole, voriconazole, itraconazole, posaconazole);
- Protease inhibitors (against the HIV virus) such as: ritonavir, indinavir, nelfinavir, saquinavir;
- Cimetidine (for treatment of heartburn, stomach ulcer, indigestion);
- Rifampicin (for treatment of tuberculosis);
- Carbamazepine (for treatment of convulsions and certain pain conditions), phenytoin (for treatment of convulsions);
- The Hypericum plant (also called St. John's wort);
- Quinidine (for treatment of heartbeat disorders);
- Medicines from the monoamine oxidase inhibitor group (MAOIs), such as: tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid, used for treatment of depression or Parkinson's disease. Also tell the doctor in case you have taken a medicine of this type within the last two weeks.

No drug interaction is expected between **Targin** and paracetamol, acetylsalicylic acid (aspirin) or naltrexone.

Use of the medicine and food: the medicine may be taken with no regard to meal times.

You should avoid drinking grapefruit juice while using 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 using the medicine may make you feel more 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: consult the doctor if you are pregnant, think you are pregnant, are planning a pregnancy or breastfeeding.

- Pregnancy:** avoid using the medicine if you are pregnant (unless the doctor instructs you otherwise). Prolonged use during pregnancy may cause withdrawal symptoms in the newborn. Use during labor may cause respiratory depression (slow and shallow breathing) in the newborn.
- Breastfeeding:** do not breastfeed during the treatment period. Oxycodone hydrochloride passes into breast milk. It is not known whether naloxone also passes into breast milk. Therefore, a risk for the breastfed baby cannot be ruled out, especially after taking multiple doses of **Targin**.

Driving and use of machinery: the use of this medicine can impair your ability to drive or operate machinery, as it may make you fall asleep and feel sleepy (especially at the beginning of treatment, when the dosage is increased, when switching from another medicine or in combination with other medicines that affect the central nervous system). Do not drive, operate machinery or participate in activities requiring alertness, if you feel drowsiness and/or any other effect that may affect alertness. Do not drive until you know how the medicine affects you. Consult the doctor if necessary.

Important information about some of the medicine's ingredients: the tablets contain lactose. If you have an intolerance to certain sugars, inform the doctor before taking this medicine (see section 6).

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 manner of treatment with the medicine. **The dosage and treatment regimen will be determined by the doctor only.** Before starting the treatment and regularly during treatment, the doctor will discuss with you what you can expect from using **Targin**, when and for how long you are to take the medicine, when to contact the doctor and when to stop using it (see also "If you stop taking the medicine").

Targin tablets have a prolonged-release mechanism – the active ingredients are released over time. Their duration of action is 12 hours.

Swallow the tablet whole, so as not to harm the slow release of oxycodone hydrochloride from the prolonged-release tablet. Do not break, chew, crush or halve the tablet! Taking non-intact tablets may lead to the absorption of a life-threatening dose of oxycodone hydrochloride (see "If you accidentally took a higher dosage" in this section).

The standard dosage is usually:

Take the tablets at set times (usually every 12 hours), as determined by the attending doctor. The doctor will adjust your dosage according to your condition and the intensity of your pain. The doctor will prescribe the minimum dose needed to control your pain.

Elderly patients: if the liver and kidney functions are normal, there is usually no need for a dosage adjustment.

Patients with impaired liver or kidney function: if you suffer from kidney function problems or from mild liver function problems, the doctor may take special caution (for example, prescribe a lower dosage). Do not use the medicine if you suffer from moderate or severe liver function impairment (see also "Do not use the medicine if" and "Special warnings regarding the use of the medicine" in section 2).

Do not exceed the recommended dose.

When switching from **Targin** to another opioid pain reliever (if the doctor decides to change treatment), your bowel function may worsen.

If you experience pain between two doses of **Targin**, refer to the doctor. You may need to receive a fast-acting pain reliever. **Targin** is not suitable for that.

If you feel that the effect of the tablets is too strong or too weak, refer to the doctor.

Method of use: for oral use. Take the tablets whole with a sufficient amount of water (about half a glass) every 12 hours (for example, at 8 am and at 8 pm). The medicine may be taken with no regard to meal times.

Crushing/halving/chewing:

Do not break, chew, crush or halve the prolonged-release tablet (see above and in section 2, "Special warnings regarding the use of the medicine").

Duration of use: do not take the tablets for a longer period of time than necessary. In prolonged treatment, the doctor will monitor you to ascertain the need for further treatment.

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. Overdose symptoms may be manifested in: constriction of pupils, slow and weak breathing (respiratory depression), drowsiness up to loss of consciousness, low muscle tone, slowed pulse rate, drop in blood pressure and brain disorder (toxic leukoencephalopathy). In severe cases, there may be loss of consciousness (coma), fluids in the lungs, collapse of the blood system (shock), which may lead to death in certain cases (conditions that require urgent medical attention).

Avoid activities that require a high level of alertness, such as driving.

If you forgot to take the medicine follow the instructions below:

If there are 8 or more hours left until taking the next dose: take the forgotten dose immediately. Take the next dose at the normal time.

If there are less than 8 hours left until taking the next dose: take the forgotten dose and wait 8 hours until the next dose.

Afterwards, try to return to the regular dosing schedule. Consult with the doctor if you are unsure.

Make sure to leave an interval of at least 8 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 state of health, do not stop treatment with the medicine without consulting the doctor.

If you stop taking the medicine: if you no longer need treatment, consult the doctor, who will instruct you how to gradually reduce the daily dosage, to reduce the risk of withdrawal symptoms, e.g., restlessness, bouts of sweating and muscle pain.

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

4. Side effects

As with any medicine, using **Targin** 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 an emergency room if the following side effects appear:

- Slow and shallow breathing (respiratory depression). Respiratory depression is the main risk in cases of overdose, it occurs mainly in elderly patients and debilitated (weak) patients.
- Severe drop in blood pressure.

Additional side effects:

Common side effects (occur in 1-10 users out of 100): abdominal pain, constipation, diarrhea, dry mouth, indigestion, vomiting, nausea, wind, decreased appetite up to loss of appetite, dizziness or a feeling of spinning, headache, hot flashes, unusual weakness, tiredness or exhaustion, skin reactions, such as itch or rash, sweating, vertigo, sleeping difficulties, drowsiness.

Uncommon side effects (occur in 1-10 users out of 1,000): abdominal bloating, abnormal thoughts, anxiety, confusion, depression, nervousness, chest tightness (especially if you already suffer from coronary heart disease), decreased or increased blood pressure, fainting, lack of energy, thirst, changes in the sense of taste, palpitations (feeling your heartbeat), bile-related pain (colic), chest pain, generally feeling unwell, pain, swelling of the hands, ankles or feet, difficulty concentrating, speech impairment, shaking, breathing difficulties, restlessness, chills, increased liver enzymes, decreased sexual drive, runny nose, cough, hypersensitivity or allergic reactions, weight loss, increased risk of injuries from accidents, increased urge to urinate, muscle pain, muscle cramps or spasms, vision impairment, epileptic seizures (especially in epileptic patients or patients prone to convulsions).

Rare side effects (occur in 1-10 users out of 10,000): increased pulse rate, dental changes, weight gain, yawning.

Side effects with unknown frequency (effects whose frequency has not yet been determined): feeling of extreme happiness (euphoria), profound drowsiness, erectile dysfunction, nightmares, dependence on the medicine, hallucinations, shallow breathing, difficulty urinating (urinary retention), aggression, withdrawal symptoms, such as agitation, tingling in the skin (feeling of pins and needles), belching, sleep apnea (breathing pauses during sleep).

Additional side effects observed with the use of medicines containing oxycodone hydrochloride only as an active ingredient, without combining it with naloxone hydrochloride:

Oxycodone may cause breathing problems (respiratory depression), reduction in the size of the eye pupils, cramping of the bronchial muscles and contraction of smooth muscles, as well as suppression of the cough reflex.

Common side effects (occur in 1-10 users out of 100): changes in behavior/personality or mood (such as depression, feeling of extreme happiness), increased or decreased activity, difficulty urinating, hiccups.

Uncommon side effects (occur in 1-10 users out of 1,000): impaired concentration, migraines, increased muscle tension, involuntary muscle contractions, intestinal obstruction, dry skin, reduced sensitivity to pain or touch, impaired coordination, changes in voice, fluid retention (edema), impaired hearing, mouth ulcers, swallowing difficulties, pain in the gums, wrong perception of reality (such as hallucinations, derealization), flushing of the skin, dehydration, agitation, decrease in the levels of sex hormones, which may affect the production of sperm in men or the menstrual cycle in women.

Rare side effects (occur in 1-10 users out of 10,000): itchy rash (urticaria), infections such as herpes or cold sores (can appear as blisters around the mouth or genitals), increased appetite, black (tarry) stool, bleeding gums.

Side effects with unknown frequency (effects whose frequency has not yet been determined): acute generalized allergic reactions (anaphylactic reactions), increased sensitivity to pain, absence of menstrual periods in women, withdrawal symptoms in the newborn, a problem that affects a valve in the intestines which may cause severe upper abdominal pain (sphincter of Oddi dysfunction), problems with bile flow, tooth decay, tolerance to the medicine.

Withdrawal (discontinuing use)

Upon discontinuing the use of **Targin**, you may experience withdrawal symptoms, including: restlessness, sleeping difficulties, irritability, agitation, anxiety, palpitations, increased blood pressure, nausea or vomiting, diarrhea, shaking, shivering or sweating.

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), which leads to the online form for reporting side effects, or by clicking on the 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. Do not induce vomiting without an explicit instruction from the doctor.

Keep this medicine in a closed and safe storage space, where other people cannot access it. The medicine may cause serious and even fatal harm to people for whom it was not prescribed.

Do not discard medicines via wastewater or household waste. When you no longer need the medicine, consult the pharmacist on how to dispose of it. These measures will help protect the environment.

- 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:** **Targin 10, 20, 30 and 40** should be stored below 25°C. **Targin 5** should be stored below 25°C, in the original package.

6. Additional information

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

Targin 5: each tablet contains about 69 mg lactose and in addition:

Stearyl alcohol, ethylcellulose N45, hydroxypropylcellulose, talc, polyvinyl alcohol partially hydrolysed, magnesium stearate, titanium dioxide (E171), macrogol 3350, brilliant blue FCF aluminium lake (E133).

Targin 10: each tablet contains about 62 mg lactose and in addition:

Stearyl alcohol, ethylcellulose N45, povidone K30, talc, polyvinyl alcohol partially hydrolysed, magnesium stearate, titanium dioxide (E171), macrogol 3350.

Targin 20: each tablet contains about 52 mg lactose and in addition:

Stearyl alcohol, ethylcellulose N45, povidone K30, talc, polyvinyl alcohol partially hydrolysed, magnesium stearate, titanium dioxide (E171), macrogol 3350, iron oxide red (E172).

Targin 30: each tablet contains about 37 mg lactose and in addition:

Stearyl alcohol, ethylcellulose N45, povidone K30, talc, polyvinyl alcohol partially hydrolysed, magnesium stearate, macrogol 3350, titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172), iron oxide black (E172).

Targin 40: each tablet contains about 104 mg lactose and in addition:

Stearyl alcohol, ethylcellulose N45, povidone K30, talc, polyvinyl alcohol partially hydrolysed, magnesium stearate, titanium dioxide (E171), macrogol 3350, iron oxide yellow (E172).

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

Oblong film-coated tablets (caplets). One side is embossed with 'OXN' and the other side is embossed with the tablet strength (5, 10, 20, 30 or 40, respectively). **The color of the tablets:** **Targin 5** – blue, **Targin 10** – white, **Targin 20** – pink, **Targin 30** – brown, **Targin 40** – yellow.

Each box contains 20 tablets in blister packs.

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

Medicine registration numbers in the national medicines registry of the Ministry of Health:

Targin 5 – 143-98-33120; **Targin 10** – 139-95-31636; **Targin 20** – 139-96-31637; **Targin 30** – 160-43-35262; **Targin 40** – 143-99-33122

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