Patient package insert in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Percocet® 5 Tablets

Name and quantity of active ingredients:
Each tablet contains:
oxycodone HCl 5 mg
paracetamol 325 mg

Percocet® 10 Tablets

Name and quantity of active ingredients:
Each tablet contains:
oxycodone HCl 10 mg
paracetamol 325 mg

Please see Section 6 for a list of the inactive ingredients.
Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have further questions, refer to your doctor or pharmacist; this medicine has been prescribed to treat you. Do not pass it on to others. It may harm them and even cause their death, even if it seems to you that their medical condition is similar to yours; this medicine is usually not recommended for children and babies; this medicine may cause addiction and substance abuse; this medicine may cause life-threatening respiratory depression; keep out of children's reach. Unintentional exposure can be life-threatening; prolonged use during pregnancy may cause withdrawal symptoms in your newborn baby; this medicine contains paracetamol which may cause liver toxicity; using this medicine at the same time with other medicines may change the concentration of Percocet in your blood and cause side effects (see additional information in Section 2: 'Before using this medicine').

Taking this medicine with benzodiazepines, other medicines which suppress the central nervous system (including narcotic drugs), or alcohol may cause deep drowsiness, breathing difficulty (respiratory depression), coma and death.

Opioid medicines may cause addiction, especially with prolonged use. It is also possible to abuse these medicines or overdose on them. An opioid overdose is often marked by slowed breathing and can cause death.
Make sure you know the name of the medicine you are taking, your dosage, how often you take it, how long you are taking it, its side effects and potential risks.
To find out more about the risk of dependence and addiction follow this link:
https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/risk/DocLib/opioids_en.pdf

1. What is this medicine intended for?

- This medicine is intended to relieve medium to acute pain.

Therapeutic group:
Oxycodone is an opioid pain reliever.
Paracetamol is a pain reliever and fever reducer.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredients (oxycodone hydrochloride or paracetamol) or to any of the other ingredients that this medicine contains (listed in Section 6).
- Using opioid medicines is contraindicated.
- There is severe respiratory depression, difficulty breathing or other lung-related problems.
- You have severe or acute bronchial asthma in an uncontrolled environment or if there is no resuscitation equipment available.
- You have a bowel blockage or suspected blockage or you have a narrowed stomach or bowel.
- You are pregnant or breastfeeding (unless you have received other instructions from your doctor).

Special warnings regarding the use of this medicine:

- Using Percocet, even at the recommended doses, can result in addiction and substance abuse that can lead to overdose and death. The risk of these effects is higher when Percocet is used at the same time as alcohol or other depressors of the central nervous system. Prolonged use may cause dependence! Do not give this medicine to anyone else. Protect from theft and misuse. To avoid withdrawal symptoms, do not stop using this medicine abruptly (see section 'If you stop taking this medicine').
- Using Percocet may cause life-threatening respiratory depression even when it is used at the recommended doses. The risk of respiratory depression is greater at the beginning of your treatment or after increasing the dose. Patients who have a severe chronic obstructive lung disease (COPD), cor pulmonale (enlarged and failing right ventricle of the heart, usually due to a chronic lung disease), significantly low lung capacity, hypoxia (lack of oxygen), hypercapnia (excess carbon dioxide) or respiratory depression since before starting treatment are at an increased risk of reduced respiratory drive, including respiratory arrest, even at the recommended doses of Percocet. Respiratory depression that is not identified and treated on time may lead to apnea and death. In addition, respiratory depression caused by using opioids may cause excess carbon dioxide in your blood and may make their sedative effect worse. If you notice respiratory depression or if you develop difficulty breathing, you must get medical help.
- When starting or renewing treatment with Percocet, talk to your doctor about the need of naloxone which is an emergency medicine for opioid overdose. Your doctor will decide on it considering your risk factors for overdose.
- Taking Percocet unintentionally, even if it is one dose, particularly by children, may cause respiratory depression and death. Store this medicine safely, out of children's reach and sight and in a location not accessible by others, including visitors. If taken unintentionally, go immediately to an emergency room.
- Opioids can cause sleep-related breathing problems including sleep apnea (dose-dependent) and sleep-related hypoxemia.
- Prolonged use during pregnancy for any reason (medical or otherwise) may cause physical dependence in your newborn baby and withdrawal symptoms in your newborn baby shortly after birth. Unlike withdrawal symptoms in adults, this can be life-threatening if not identified and treated on time.
- Using Percocet at the same time with benzodiazepines or other central nervous system depressors, including alcohol, may cause low blood pressure, deep sedation, respiratory depression, coma and death. Do not use these medicines together unless supervised by a doctor. (See section: 'Other medicines and Percocet').

- Using Percocet with inhibitors of cytochrome P450 3A4 and P450 2D6 in the liver (such as erythromycin, ketoconazole, ritonavir and others) may increase the concentration of oxycodone in your blood and make the side effects become worse or last longer. This may lead to life-threatening respiratory depression. This is particularly true when the inhibitor medicine is added after a stable dose of Percocet has been reached. In the same way, stopping a medicine that increases cytochrome P450 3A4 activity in your liver (such as rifampin, carbamazepine and phenytoin) may increase the concentration of Percocet in your blood and make the side effects become worse or last longer. Alternatively, using this medicine together with medicines that increase the activity of cytochrome P450 3A4 in your liver or stopping a medicine that inhibits the activity of cytochrome P450 3A4 in your liver, may reduce the concentration of Percocet in your blood making the medicine less effective or causing withdrawal symptoms in a patient who has developed a dependence on Percocet.
- Percocet may cause adrenal insufficiency which may be a life-threatening condition. The following may be signs of this: nausea, vomiting, lack of appetite, tiredness, weakness, dizziness and low blood pressure. If you have these symptoms, you must get medical help as soon as possible.
- Opioid medicines tend to cause an increase in carbon dioxide concentration and the pressure inside your skull may increase as a result. Previous pressure in the skull or brain tumors may make the condition worse.
  This medicine may make it difficult to diagnose worsening conditions or it may mask worsening conditions in patients with head injuries. Do not use in patients in a stupor or in a coma.
- Paracetamol may cause liver damage and acute liver insufficiency; in some cases it may cause the need for a liver transplant and death, when: given at a higher than the recommended dose - when the maximum daily dose (4000 mg a day) is exceeded and/or you take additional medicines that contain paracetamol. Do not use more than one paracetamol product at the same time; given to patients with an undiagnosed liver disease; drinking alcoholic beverages during the course of treatment; taking other medicines that affect your liver function; the risk of acute liver insufficiency is higher in patients with an existing liver disease.
- To avoid a paracetamol overdose or poisoning, do not take additional fever and pain relief medicines or cold medicines without consulting your doctor or pharmacist.
- Do not take additional paracetamol medicines and/or additional products that contain paracetamol.
- Avoid taking other opioid pain relievers (such as pentazocine, nalbuphine, butorphanol, and buprenorphine) together with Percocet. Using these medicines together with Percocet may reduce the pain-relief effect of Percocet and/or cause withdrawal syndrome.
- This medicine may cause a sharp drop in your blood pressure and you may experience dizziness or fainting particularly when standing (orthostatic) and when getting up suddenly from a reclining or sitting position. You are advised to get up slowly to keep this effect to a minimum. This risk is higher in patients who are less able to regulate their blood pressure, for example patients with a low blood volume or after taking certain medicines that depress the central nervous system, such as phenothiazines and anesthetics.
- Use with caution in elderly, emaciated, or weak patients, because these populations are at a greater risk of life-threatening respiratory depression.
- This medicine may make it more difficult to make a diagnosis or it may mask the clinical condition in patients with acute abdominal disorders.

- This medicine may make spasms or seizures worse.
- If you ever developed skin-related side effects as a result of taking medicines that contain paracetamol, do not take medicines that contain paracetamol so that you do not get severe skin effects again. In rare cases, paracetamol may cause severe skin side effects such as exanthemous pustulosis (AGEP), Stevens–Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) which can cause death. Stop using this medicine on the first appearance of a rash or other sign of hypersensitivity.
- There are reports of hypersensitivity, anaphylaxis, when using paracetamol. Signs of this include: swelling of the face, mouth, throat, respiratory distress, urticaria (hives), rash, itch and vomiting. There are rare reports of anaphylaxis that required emergency treatment. If you experience any of these signs, stop taking the medicine immediately and get medical attention.
- Oxycodone and other opioid medicines cause reduced motility of the bowels which may cause severe constipation.
- Use this medicine with caution in patients who have pancreas or gall bladder problems. Opioids may cause a rise in blood levels of the enzyme amylase.
- Percocet may cause serotonin syndrome, which is a rare but life-threatening syndrome, that happens as a result of using opioids together with serotonergic medicines such as SNRI/SSRI (increase serotonin levels), TCAs, triptans, 5-HT3 blockers, medicines that affect serotonin transmission in the nerves (such as mirtazapine, trazodone, tramadol), certain muscle relaxants, monoamine oxidase inhibitors (MAOI) (used to treat psychiatric disorders) and other substances such as linezolid and methylene blue for infusion. Tell your doctor if you are using or plan to use serotonergic medicines. If you develop signs of the syndrome, get medical help immediately.
- Using opioids and monoamine oxidase inhibitors (MAOI) such as phenelzine, tranylcypromine and linezolid may cause serotonin syndrome or opioid toxicity (such as respiratory depression or coma). Using Percocet is not recommended in people using MAOI medicines or patients who have stopped using MAOI medicines within the last 14 days.
- Avoid taking high doses (within recommended limits) of this medicine while fasting.

Before using Percocet, tell your doctor if:

- You have or have had in the past impaired function of your respiratory system or lungs [such as asthma, hypoxia (lack of oxygen), hypercapnia (excess carbon dioxide), respiratory depression, chronic obstructive pulmonary disease, cor pulmonale (enlarged and failing right ventricle of the heart, usually as a result of a chronic lung disease)]; you have circulatory shock; you have or have had in the past impaired function of the heart and/or blood vessels; you have or have had in the past impaired function of the liver or kidney/urinary system or if you have problems passing urine; you have or have had in the past impaired function of the thyroid (hypothyroidism); you have or have had in the past a head injury, increased pressure in the skull or brain tumors; you have or have ever had spasms; you have a biliary tract disease including acute inflammation of the pancreas (pancreatitis); you have a depressed central nervous system; you have acute alcoholism; you have or have ever had jaundice; you or a member of your family, are experiencing or have experienced chemical substance abuse (including drug or alcohol addiction); you have ever had an opioid overdose; you or a member of your family, have or have had in the past a mental disease (such as depression); you have acute

abdominal problems; you are sensitive to any food or medicine; you are pregnant or breastfeeding.

Tests and follow-up

Paracetamol may cause false results in home glucose (sugar) tests.

Other medicines and Percocet

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

Medicines that inhibit the liver enzyme cytochrome P450 3A4 and P450 2D6, such as erythromycin, ketoconazole and ritonavir (see section 'Special warnings regarding the use of this medicine'); medicines that increase the activity of cytochrome P450 3A4 in the liver (for example rifampicin, carbamazepine, phenytoin); nonsteroidal anti-inflammatory drugs (NSAIDs); medicines that affect or depress the central nervous system [such as other opioid pain relievers, general anesthesia medicines, phenothiazines, sedatives, benzodiazepines, alcohol, hypnotic medicines, anti-anxiety medicines, muscle relaxants, medicines for treating psychiatric or mental disorders (see section 'Special warnings regarding the use of the medicine')]; medicines that affect serotonin levels, such as: SSRIs, SNRIs, tricyclic anti-depressants, triptans, 5-HT3 receptor antagonists, other medicines that affect the serotonin system (such as mirtazapine, trazodone, tramadol), certain muscle relaxants (such as cyclobenzaprine, metaxalone), monoamine oxidase inhibitors (MAOI) intended for treating psychiatric disorders and other monoamine oxidase inhibitors (such as linezolid, intravenous methylene blue, phenelzine, tranylcypromine). Using these medicines with opioids may cause serotonin syndrome; tell your doctor if you have used MAOIs in the last 14 days. Using these medicines with opioids may cause serotonin syndrome or opioid toxicity (respiratory depression, coma); skeletal muscle relaxants. Using Percocet may increase the activity of skeletal muscle relaxant medicines and make the respiratory depression worse; metoclopramide or domperidone (for treating nausea, vomiting and other digestion problems), beta-blockers (propranolol). Propranolol may increase the effect of the paracetamol; diuretics - opioids may reduce the effectiveness of diuretic medicines; loop diuretics - paracetamol may reduce their effect; cough and cold medicines; other opioids: pentazocine, nalbuphine and butorphanol - may reduce the pain-relieving effect of Percocet or cause withdrawal symptoms; anticholinergic medicines - using this medicine together with anticholinergic medicines may increase urinary retention and/or severe constipation (may result in a blocked bowel); contraceptive pills - reduce the half-life of paracetamol and assist with fast removal from the plasma; activated carbon - reduces the absorption of paracetamol when taken immediately after an overdose; lamotrigine- using Percocet may reduce the therapeutic effects of lamotrigine because its concentration in the blood is reduced; probenecid (for treating gout) - may slightly increase the therapeutic effectiveness of paracetamol; zidovudine - using Percocet may reduce the therapeutic effects of zidovudine; anticoagulants, particularly warfarin; chloramphenicol (an antibiotic); cholestyramine (for reducing excess fat in the blood).

Each of the components of Percocet (oxycodone and paracetamol) may affect the results of early detection tests of cocaine or marijuana in the urine. More specific tests must be used to confirm the presence of these substances in the body.

Using this medicine and alcohol consumption:

Do not consume alcohol. Drinking alcohol while on this medicine may increase the risk of damage to the liver. In addition, using this medicine together with alcohol may increase the depressing effect on the central nervous system, sedation, respiratory depression and risk of death.

Pregnancy, breastfeeding and fertility:

Percocet may harm your unborn baby. If you are pregnant or are planning to become pregnant, consult your doctor before using this medicine.
Opioids can pass to your unborn baby and may cause respiratory depression in your unborn baby. In addition, opioids may cause dependence in your unborn baby. After birth, your newborn may experience severe withdrawal symptoms which can be life-threatening. Signs of withdrawal symptoms in newborns include irritability, hyperactivity and irregular sleeping patterns, shrill crying, chills, vomiting, diarrhea and not gaining weight. The emergence, duration and severity of withdrawal symptoms in your newborn depend on the type of opioid used, how long it was used, at what times, what amounts the mother used lately, and how fast the newborn is able to break down the substance.
Babies born to mothers who are opioid-dependent will also develop dependence and may experience difficulty breathing and signs of withdrawal.
Percocet is not recommended to women during labor and just before they deliver the baby because of possible respiratory depression in the newborn. Opioid pain-relievers, including Percocet, may extend the duration of labor because the strength, duration and frequency of contractions are reduced. However, this is not a consistent effect, and Percocet may also shorten labor.
Usually, you are not allowed to breastfeed while using this medicine because of its sedative effect and its depressive effect on breathing in your newborn.
Your doctor will weigh the benefits of breastfeeding, such as your baby's development and health, against the mother's needs and the drawbacks of side effects in babies who are breastfed by mothers on Percocet. Oxycodone, one of the active ingredients in this medicine, passes into breastmilk in small amounts and there have been rare reports of sleepiness, tiredness and difficulty breathing in babies who were breastfed by women taking this medicine. In addition, breastfed babies may experience withdrawal symptoms when their mother stops the medicine or when their mother stops breastfeeding. Also paracetamol passes into breastmilk in low concentrations.
Fertility - Chronic use of opioids may impair fertility. It is unknown if this impairment is reversible or not.

Driving and using machines:

Using this medicine may impair your alertness and the physical and mental abilities you need to perform dangerous actions. So, exercise caution when driving a car, operating dangerous machines and performing any other activity that requires alertness. When using Percocet together with other benzodiazepines or with other central nervous system depressants, you are advised to avoid driving and operating dangerous machines until the effects of taking these medicines together have become clear.

Use in children:

Efficacy and safety of use in children has not been tested.

Use in the elderly:

Elderly patients (over 65) may be more sensitive to Percocet and its side effects; the greatest risk is respiratory depression. Use with caution and according to the dose prescribed by your doctor (you may need a lower dose). Your doctor will consider the concomitant effect of a disease or medical treatment and the higher incidence of reduced liver, kidney, or heart function in this population.

Use in patients with impaired liver function:

Patients with impaired liver function will have their dose adjusted by their doctor (they may need a lower dose) and will be monitored for side effects such as respiratory depression, sedation and low blood pressure.

Use in patients with impaired kidney function:

Patients with impaired kidney function will have their dose adjusted by their doctor (they may need a lower dose) and will be monitored for side effects such as respiratory depression, sedation and low blood pressure.

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 about the dose and how to take this medicine. **Only your doctor will determine your dose and how you should take this medicine. The recommended dose is usually:**
One tablet every six hours, as needed. Do not exceed 4 grams of paracetamol a day.
Maximum dose: Percocet 5: 12 tablets a day. Percocet 10: 6 tablets a day.
Patients with impaired liver or kidney function will have their dose adjusted by their doctor (they may need a lower dose).
Do not stop using Percocet abruptly after having used it for several weeks. Consult your doctor about stopping this medicine gradually. Do not change your dose without consulting your doctor.
Do not exceed the recommended dose.
Do not chew! To make it easier to swallow, you may, if necessary, split the tablet immediately before you use it. Swallow both halves together, immediately after you have split the tablet. Swallow the medicine with a large amount of water. Do not keep the medicine in your mouth longer than the time it takes to swallow it.
If you have taken an overdose, or if a child has accidentally swallowed some medicine, go immediately to a doctor or proceed to a hospital emergency room, even if you feel well. Bring the medicine package with you. Signs of oxycodone overdose are: narrowed pupils, respiratory depression, losing consciousness, extreme sleepiness which progresses to stupor or coma, relaxed skeletal muscles, cold and moist skin, occasionally lung edema, slow heart rate (bradycardia), low blood pressure, partial or complete blockage of the respiratory tract, unusual snoring, and death. Other signs are widened pupils together with hypoxia (lack of oxygen). Paracetamol overdose may lead to dose-dependent liver necrosis that may be life-threatening. Kidney necrosis, coma due to low blood-sugar level, and coagulation problems may also occur. Early signs of toxic injury in the liver are: nausea, vomiting, excessive sweating, and feeling generally unwell. Clinical and laboratory signs of liver necrosis may appear only 48-72 hours after taking the medicine.
Naloxone (a medicine used as an emergency treatment for opioid overdose) has a temporary effect, so get immediate medical help in any case or suspected case of opioids' overdose, even if naloxone was taken.
If you forget to take this medicine at the scheduled time, take a dose as soon as you remember, but never take two doses together!
Adhere to the treatment as recommended by the doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor or pharmacist.
If you stop taking this medicine
Consult your doctor before you stop a long-duration high-dose treatment. Patients who have been treated for several days to several weeks and do not need treatment any more must stop taking this medicine gradually. Do not stop taking this medicine on your own without first building a personalized gradual withdrawal program with your doctor. Stopping this medicine abruptly or greatly reducing the dose may cause withdrawal symptoms, including: restlessness, watering eyes, runny nose, yawning, excessive sweating, chills, muscle pain and widened pupils, irritability, anxiety, back pain, joint pain, weakness, stomach cramps, insomnia, nausea, anorexia, vomiting, diarrhea, increased blood pressure, breathing rate, or heart rate. Withdrawal syndrome may also occur as a result of using medicines that suppress opioid activity (such as

naloxone, nalmefene) or other opioid pain relievers that work differently (pentazocine, butorphanol, nalbuphine, buprenorphine).
Stopping this medicine abruptly or greatly reducing the dose may lead to uncontrolled pain and suicide.
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 about using this medicine, consult your doctor or the pharmacist.

4. Side effects

Like all medicines, taking Percocet may cause side effects in some people. Do not be alarmed by this list of side effects. You may not experience any of them.
Serious side effects:
Stop using this medicine immediately and consult a doctor or emergency medical services if:
you experience temporary disruption of breathing (apnea); you experience respiratory arrest; you experience circulatory depression; you develop serotonin syndrome while using this medicine together with medicines that affect serotonin release (a condition that results from a dangerous increase in serotonin levels in the body and which has the following signs: rise in body temperature, fast heartbeat, chest pain, headache, altered mental state such as confusion, involuntary movements, hallucinations, tremor, chills, feeling faint, sweating, nausea, diarrhea, stiff muscles and difficulty walking); you have allergic reactions (such as swelling of the face, lips, tongue, throat and/or limbs, respiratory distress or difficulty swallowing, hives, rash, itch and vomiting), shortness of breath (anaphylactic reaction); in rare cases, paracetamol can cause acute skin diseases. Signs of these may include: redness, rash, blisters, wide-spread skin damage. Acute skin side effects may occur even if you have previously taken without issue medicines that contain the active ingredient paracetamol. If you experience skin side effects, stop the treatment and consult a doctor immediately; you experience signs of changes in your circulatory blood system such as: bleeding, bruises, getting inflammations more easily because you have fewer red blood cells, reduced number of neutrophils, reduced number of platelets and reduced number of all blood cells. Rare cases have been reported of a sharp and dangerous drop in leucocytes (agranulocytosis) when using paracetamol; you experience respiratory depression; you experience reduced blood pressure; you experience shock; you have liver or kidney necrosis or diabetes-related coma; you experience overdose side effects.
Additional side effects:
the most common reactions: dizziness, dozing or feeling calm, nausea and vomiting, feeling euphoric or dysphoric, constipation and itch; endocrine reactions: lack of male hormone (androgen) which is expressed as reduced libido, impotence, absence of menstruation or infertility; general body reactions: anaphylactic reaction, allergic reaction, feel unwell, exhaustion, tiredness, chest pain, fever, low body temperature (hypothermia), thirst, headache, excessive sweating, overdose; cardiovascular reactions: low blood pressure, high blood pressure, fast heart rate (tachycardia), orthostatic hypotension, slow heart rate (bradycardia), palpitations, heart rhythm disorders (dysrhythmia; nervous system reactions: stupor, tremor, prickling (paresthesia), reduced sensitivity to touch, lethargy, seizures, anxiety, mental disorder, agitation, brain edema, confusion, dizziness; reactions related to fluids and electrolytes: dehydration, excess potassium in the blood, metabolic ketoacidosis, respiratory alkalosis; digestive system reactions: indigestion, taste disorders, stomachache, swollen stomach, excessive sweating, diarrhea, dry mouth, flatulence, digestive tract disorders, nausea, vomiting, inflammation of the pancreas, blocked bowel; liver reactions: temporary increase in liver enzymes, increased bilirubin, liver inflammation, liver failure, jaundice, liver toxicity, liver disorders; hearing and balance reactions: hearing loss, ringing in your ears; blood vessel reactions: reduced number of platelets

(thrombocytopenia), reduced number of white blood cells, red blood cells and platelets at the same time (pancytopenia), reduced number of neutrophils (a type of white blood cells), and hemolytic anemia. Rare cases of agranulocytosis (severe deficiency in white blood cells) have been reported with paracetamol use; hypersensitivity reactions: acute allergic reaction (anaphylaxis), fast swelling (edema) of the skin (angioedema), asthma, bronchospasm, throat edema, hives (urticaria), allergic reaction (anaphylactoid); metabolic reactions: low blood sugar, high blood sugar, acidosis, alkalosis; skeleton and muscle reactions: muscle pain, muscle cells break down (rhabdomyolysis); eye reactions: contracted pupils, vision disorders, redness of the eye; psychiatrist reactions: medicine dependence, medicine abuse, medicine tolerance, insomnia, confusion, anxiety, agitation, reduced consciousness, irritability, hallucinations, sleepiness, depression, suicide; respiratory system reactions: bronchospasm, shortness of breath, increased frequency and depth of breathing, lung edema, rapid breathing, aspiration (inhaling) of foreign substances (food, saliva, acids) into the respiratory tract, inadequate ventilation (hypoventilation), throat edema; skin reactions: redness, hives, rash, flushing; urinary and genital reactions: inflammation of the interstitial tissue (the tissue between the cells) in the kidneys, papillary necrosis, protein in the urine, kidney insufficiency and kidney failure, urinary retention; adrenal insufficiency; at high doses, dose-dependent liver necrosis may occur which can be life-threatening. Necrosis of the kidney tubules and hypoglycemic coma may also occur.

If any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Medication' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by following this link: https://sideeffects.health.gov.il

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this and all other medicines, in a closed place out of reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor! 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; store below 25˚C; when you no longer need these tablets consult your pharmacist about how to dispose of them.

6. Additional information

In addition to the active ingredients this medicine also contains:

microcrystalline cellulose, pregelatinized starch, stearic acid, magnesium stearate, povidone. Percocet 10 tablets also contain**:** color D&C yellow # 10.

What the medicine looks like and what are the contents of the package:

Percocet 5: Flat, round, white tablets with a score line on one side; packaged in blisters in a carton. Each package contains 10, 20, or 1000 tablets.

Percocet 10: Flat, round, yellow tablets with a score line on one side; packaged in blisters in a carton. Each package contains 10 or 20 tablets.

Not all package sizes are available.

Manufacturer and registration holder's name and address: Taro Pharmaceutical Industries Ltd., 14 Hakitor St., Haifa Bay 2624761

Registration number of the medicine in the Ministry of Health National Drug Registry:

Percocet 5: 023 99 21468 **Percocet 10:** 139 21 31414

Revised in December 2020.