

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

The medicine is dispensed with a doctor's prescription only

**Name of the medicine, form and strength:
Parotin 20 mg tablets**

The active ingredient and its quantity:

Each tablet of Parotin 20 mg contains:

Paroxetine (as hydrochloride) 20 mg

Inactive ingredients and allergens (see section 6)

Read the entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have any other 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.

Antidepressants and anti-anxiety medicines increase the risk for suicidal behavior and thoughts in children, adolescents and young adults up to the age of 25.

Upon the beginning of treatment with the medicine, patients of all ages and their relatives should pay attention to behavioral changes such as: increased depression, suicidal thoughts, aggressiveness and the like.

If such changes occur, contact the doctor immediately.

1. What is the medicine intended for?

Therapeutic activity:

The medicine is intended for treatment of symptoms of depression of all types, including depression accompanied by anxiety, and prevention of relapse.

Treatment of symptoms and prevention of relapse of obsessive-compulsive disorder (OCD) and panic disorders with or without agoraphobia. Treatment of symptoms of social phobia, post-traumatic stress disorder, generalized anxiety disorder.

Therapeutic class: selective serotonin reuptake inhibitor (SSRI).

2. Before using the medicine

☒ Do not use this medicine if:

- You have a known hypersensitivity to any of the medicine's ingredients or if you had an allergic reaction to any of its ingredients.

- You are being treated simultaneously with medicines from the monoamine oxidase (MAO) inhibitors group (for depression) or within 14 days of discontinuing treatment with them, or with an antibiotic called Zyvoxid (linezolid).
- You are being treated simultaneously with thioridazine.
- You are being treated simultaneously with pimozide.

Special warnings regarding the use of the medicine:

☒ Do not stop taking this medicine abruptly without consulting your physician!

There is an increased risk of bone fractures in patients taking medicines of this type. The risk is greater during the early stages of treatment.

☒ Before treatment with Parotin, tell the doctor if:

- You are suffering, or have suffered in the past, from impaired function of: the heart and/or vascular system, the eyes (glaucoma), the kidney/urinary tract, the liver.
- You are suffering from epilepsy, convulsions or mania.
- You bruise or bleed easily, or are taking a medicine that increases bleeding.
- You have been diagnosed as schizophrenic and are receiving drug treatment.
- You are sensitive to any type of food or medicine.

☒ Children and adolescents:

This medicine is not usually intended for use in children and adolescents below 18 years of age.

In children and adolescents below the age of 18 who took this medicine, an increase was observed in side effects such as suicide attempts, suicidal thoughts and hostility. Nevertheless, your physician can prescribe this medicine for you if he thinks it will benefit you. If your physician prescribed the medicine for you and you are interested in discussing it with him, consult him again.

You must report to your physician if some of the above side effects appear or get worse. There are no long-term data concerning growth and development, maturation, cognitive behavior and behavioral development in this age group.

☒ Tests and follow-up:

It is recommended that patients and their family members pay attention to behavioral changes such as: increased depression, suicidal thoughts, aggressiveness and the like. If such changes occur, refer to your physician

immediately.

This recommendation should be strictly followed in young patients 18 to 24 years of age. Information from clinical trials has shown that young adults, especially those suffering from depression, are likely to be at a higher risk of having suicidal behavior (including suicide attempts) when they are treated with this medicine. Most of the suicide attempts in clinical trials on depression occurred in patients between 18 to 30 years of age.

In children, adolescents and young adults up to the age of 24 who took antidepressants, there was an increase in side effects such as: suicide attempt, suicidal thoughts and hostility.

☒ Drug-drug interactions:

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

- Medicines affecting the central nervous system (e.g.: sedatives, hypnotics, drugs for Parkinson's disease - e.g. procyclidine and anti-epileptic drugs)
- Anti-psychotics
- Medicines for prevention of blood clots
- Antidepressants
- Tramadol
- St. John's Wort
- Lithium
- Medicines for migraine from the triptan group, such as sumatriptan
- Tryptophan - an amino acid found in foods, solutions for parenteral nutrition and food supplements
- Do not use together with MAO inhibitors or within two weeks of cessation of treatment with MAO inhibitors. Do not start treatment with MAO inhibitors during the two weeks following cessation of treatment with Parotin.
- Medicines for treatment of irregular heartbeat
- Medicines for treatment of schizophrenia
- Metoprolol
- Atomoxetine
- Tamoxifen
- Fentanyl (used for anesthesia or for treatment of chronic pain)
- Combination of fosamprenavir and ritonavir for treatment of human immunodeficiency virus (HIV)
- Antidepressants belonging to the SSRI and SNRI groups may cause serotonin syndrome (rare) (see Side effects that require special attention). The syndrome may occur more frequently if you are taking concomitantly

other medicines which affect the central nervous system (see above).

☒ Use of Parotin with food:

It is better to take the medicine with breakfast.

☒ Use of Parotin and alcohol consumption:

Do not drink wine or alcoholic beverages during treatment with this medicine.

☒ Pregnancy, breastfeeding and fertility:

Do not use this medicine if you are pregnant, think you might be pregnant or breastfeeding, unless you have consulted your physician and discussed with him the risk versus the benefit of taking this medicine.

Use of medicines belonging to this group (antidepressants) may affect the general condition of your baby.

If you are being treated with this medicine and are planning to become pregnant or are pregnant, do not discontinue treatment on your own - consult your physician.

Medicines like Parotin may affect the sperm.

While taking this medicine, a reduction in fertility may occur in some men.

In clinical trials, when the medicine was taken during the first few months of pregnancy, there was an increase in birth defects, especially heart defects. Also, when pregnant women received SSRIs (including Parotin) during the pregnancy, there was a complication in the newborns - prolonged pulmonary hypertension. In addition, when the medicine was taken during pregnancy, cases of early delivery were reported, though it is not known whether this was due to the use of the medicine.

In the event that the medicine is taken throughout the pregnancy until birth, the following side effects may occur in the newborns, although it is not known if these symptoms can be attributed to the medicine: difficulty sleeping, constant crying, agitation, feeding difficulties, excessive sleepiness, tremor, vomiting, low blood sugar levels, breathing difficulties, bluish/purplish discoloration of the skin, spasms, increased or poor muscle tone, difficulty with regulation of body temperature. These effects are transient.

If your baby experiences these symptoms, consult the attending physician as soon as possible.

Serotonin syndrome: high fever, nervousness, sweating, heightened reflexes, increased heart rate, irritability, confusion, tremor or strong muscle cramps - contact the doctor immediately.

☒ Driving and operating machinery:

Use of this medicine may impair alertness and therefore caution should be exercised when

driving a car, operating dangerous machinery and in any activity which requires alertness. Children should be cautioned against riding a bicycle or playing near a road etc.

3. How should you use Parotin?

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

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

Dosage:

Dosage is according to the physician's instructions only. Do not exceed the recommended dose.

This medicine is not usually intended for administration to children and infants.

This medicine should be used at set intervals as determined by the treating doctor.

Method of administration: The tablet should be swallowed with some water. It is better to take the medicine with breakfast.

Crushing/halving/chewing:

If necessary, the tablet may be crushed and immediately swallowed with water.

The tablet can be halved.

If you accidentally took a higher dose or if a child accidentally swallowed the medicine, immediately proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine at the appointed time, take a dose on the following morning. Never take two doses together!

If you stop taking the medicine

Even if there is an improvement in your health, do not discontinue this medicine abruptly without consulting your physician.

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

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

4. Side effects

As with any medicine, using Parotin may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Dry mouth, nausea, vomiting, tremor, feeling shaky, sexual dysfunction (impotence, premature ejaculation), diarrhea, tendency to fall asleep, fatigue, constipation, blurry vision, sweating, dizziness, loss of appetite, inability to fall asleep, abnormal dreams (including

nightmares), yawning, restlessness, anxiety, elevated blood cholesterol levels, weight gain, headache, dilated pupils.

Side effects that require special attention:

Rare effects - refer to your physician:

high intraocular pressure (glaucoma), irresistible urge to move the legs (restless legs syndrome), difficulty urinating or urinary incontinence, hemorrhaging or bleeding easily, serotonin syndrome (including the following symptoms: nervousness, confusion, sweating, hallucinations, heightened reflexes, muscle spasms, shaking and increased heart rate), involuntary movements, emotional outbursts (fits), confusion, manic reactions (such as emotional outbursts, hyperactivity and unrestrained behavior), abnormal production of breast milk, low sodium concentration in patients over 65 years of age - may cause a reduction of sodium in the blood, resulting in symptoms such as weakness, tiredness and drowsiness, increased ADH production causing fluid retention, change in liver enzyme levels and severe liver problems (nausea, vomiting, loss of appetite, a general ill feeling, fever, yellowing of the skin and the eyes, dark urine).

Allergic reactions, including: rash, itching, urticaria, swelling of the face, lips, mouth or tongue, difficulty swallowing or breathing. In such cases, refer to the physician immediately! Dizziness or feeling faint upon standing up suddenly (due to a drop of blood pressure). Swelling of the hands and feet, skin sensitivity to sunlight, hallucinations, stomach bleeding, decrease in platelet count.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your 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 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. Do not induce vomiting without an explicit instruction from the doctor. Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Storage:

Store in a dry place at a temperature below 25°C.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Calcium hydrogen phosphate dihydrate, povidone, starch, magnesium stearate, white opadry, macrogol.

What does the medicine look like:

A round white tablet, with a score line on one side.

10, 15, 20, 30, 50 or 60 tablets in a package. Not all package sizes may be marketed.

Manufacturer and license holder: CTS Chemical Industries Ltd., P.O. box 385, Kiryat Malachi.

This leaflet from 05/2020 is formatted according to the requirements of the Ministry of Health, and its content matches the leaflet of the original preparation, which was checked and approved by the Ministry of Health in 01/2010. Registration number of the medicine in the National Drug Registry of the Ministry of Health: 133-48-31068-00



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