PATIENT LEAFLET IN CORDANCE WITH THE PHARMACISTS' REGULATION (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Parotin 20 mg film-coated

Each film-coated tablet contains: Paroxetine (as Hydrochloride) 20 mg For a list of inactive ingredients and allergens see section 6 "Additional nformation"

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 ma harm them even if it seems to you that their medical condition is similar.

Antidepressants and anti-anxiety medicines increase the risk of suicidal behavior and thoughts in patients up to the age of 25. When beginning treatment with the medicine, patients of all ages and their relatives should pay attention to behavioral changes such as: worsening of the depression, suicidal thoughts, aggressiveness and the like. If such changes occur, contact the doctor immediately.

1. What is the medicine ntended for?

Parotin is intended for the treatmen of adults with maior/clinical depressive disorder and/or anxiety disorders. The anxiety disorders that Parotin is used to treat are: obsessive compulsive disorder, panic disorder, social anxiety, post-traumatic stress disorder and generalized anxiety disorder.

Therapeutic class: Selective serotonin reuptake inhibitors (SSRI).

It is not fully understood how Parotin and other selective serotonin reuptake inhibitors work, but they may help by increasing the level of serotonin in the brain. Proper treatment of depression or anxiety disorders is important to help vou feel better.

. Before using the medicine Do not use this medicine if:

- You are sensitive (allergic) paroxetine or to any of the othe ngredients this medicine contains (for the list of inactive ingredients see section 6).
- You are taking medicines called monoamine oxidase inhibitors (MAOIs including moclobernide and methylthioninium chloride (methylene blue)) or if you have been taking them in the past ty weeks. Your doctor will advise you how you should begin taking Parotin once you stop taking monoamine oxidase inhibitors.
- You are taking an antipsychotic medicine called thioridazine or an anti-psvchot medicine called pimozide.
- If any of these apply to you, te the doctor without taking Parotin

Special warnings regarding the use of the medicine: Before treatment with Parotin, tell the doctor if:

- You are taking any other medicines (see in section 2 "Drug interactions").
- You are taking tamoxifen to treat breast cancer or fertility problems. Parotin may make tamoxifen less effective, so your doctor may recommend that you take a different antidepressant.
- You have a kidney. liver or heart

- You have a family history of QT prolongation heart diseases such potassium levels or low magnesium of your depression or anxiety levels
- You have epilepsy or you have a history of seizures or convulsions
- You have ever had episodes of mania (overactive behavior and noughts).
- You are receiving electro-convulsive antidepressants, since all these therapy (ECT)
- You have a history of bleeding, or you are taking other medicines that may increase the risk of bleeding (these medicines include medicines) used to thin the blood such as warfarin, anti-psychotic medicines such as perphenazine or clozapine, tricyclic antidepressants, medicines used to treat pain and inflammation alled non-steroidal antinflammatory drugs (NSAIDs) such acetylsalicylic acid, ibuprofen, celecoxib, etodolac, diclofenac, meloxicam).
- You have diabetes.
- You are on a low sodium diet
- You have glaucoma (intraocular pressure).
- You are pregnant or planning t become pregnant (see in section "Pregnancy, breastfeeding and
- You are under 18 years of age (see in the section "Children and adolescents under the age of 18").
- If any of these apply to you and you have not vet consulted with your changes in your behavior doctor and ask what you should do about taking Parotin.
- Children and adolescents under the age of 18:
- o not use Parotin in children and adolescents under 18 years of age. Parotin is not intended and must not be Other patients develop phenomena An abnormality known as QT interval used to treat children and adolescents. called serotonin syndrome, or prolongation has been found in the since clinical studies have found a link neuroleptic malignant syndrome results of the cardiac ECG follow-up between Parotin and an increased risk which include some or all of the of suicidal and hostile behavior.

The use of Parotin has not been tested confusion, feeling restless, sensation in children under 7 years of age as heart failure, low heart rate or low **I Suicidal thoughts and worsening** disorder:

If you are depressed and/or have anxiety disorders, you may sometimes have thoughts of harming yourself or committing suicide. These thoughts may be increased when first starting medicines take time to work. Usually about two weeks, but sometimes even lonaer

You may have thoughts of harming vourself or committing suicide at a aher probability i

You have previously had thoughts about harming yourself or committing suicide.

You are a **voung adult.** Information from clinical trials has shown an increased risk of suicidal behavior in adults under 25 years of age with psychiatric conditions who were treated with antidepressants If you have thoughts of harming

- vourself or committing suicide. refer to your doctor or go to a hospital immediately You may find it helpful to tell a
- relative or close friend that you are depressed or that you have an anxiety disorder, and ask them to read this leaflet. You may ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about doctor about them, go back to your II Important side effects seen with

Some patients who take Parotin develop a phenomenon called akathisia, which includes a feeling of restlessness and a feeling as if they cannot sit or stand still following symptoms: a strong feeling of nervousness or irritability, a sense o

of heat sweating tremors chills hallucinations (strange visions or sounds), muscle stiffness, sudden muscle spasms or a fast heartbeat. There may be aggravation that leads to loss of consciousness. If you notice any of these symptoms, refer to your doctor. For more information on these or other side effects of Parotin, see section 4 "Side effects". Medicines such as Parotin (referred to as selective serotonin reuptake inhibitors, SSRIs) may cause symptoms of sexual dysfunction (see section 4 "Side effects"). In some cases, these symptoms have continued after stopping the treatment.

Drug interactions:

Certain medicines can affect the way Parotin works, or increase the probability that you will have side effects. Parotin may also affect the way certain other medicines work. 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:

- Medicines called monoamine oxidase inhibitors (MAOIs including moclobemide and methylthioninium chloride (methylene blue)) – see in section 2 Do not use this medicine if".
- Medicines known to increase the risk of changes in the cardiac electrical activity (such as the antipsychotic medicines thioridazine and pimozide) – see in section 2 "Do not use this medicine if".
- Acetylsalicylic acid (aspirin) ibuprofen or other medicines called NSAIDs (non-steroidal anti-inflammatory drugs) such as celecoxib, etodolac, diclofenac and meloxicam, used to treat pain and inflammation.
- Tramadol, buprenorphine and pethidine – pain relievers.

- Buprenorphine in combination with naloxone – an alternative treatment for opioid addiction.
- Medicines called *triptans*, such as sumatriptan, used to treat migrain
- Other antidepressants including SSRIs, tryptophan and tricyclic antidepressants such as clomipramine, nortriptyline and desipramine.
- A nutritional supplement called trvptophan.
- Mivacurium and suxamethonium (used in anesthesia)
- Medicines such as lithium. risperidone, perphenazine, clozapine (called anti-psychotics) used to treat certain psychiatric conditions.
- Fentanyl for use in **anesthesia** or for the treatment of chronic pain.
- A combination of fosamprenavir and ritonavir. used to treat human immunodeficiency virus (HIV) infection.
- Hypericum (St. John's wort), an herbal remedy for depression phenobarbital, phenytoin, sodium
- valproate or carbamazepine, used to treat seizures or epilepsy.
- Atomoxetine, used to treat attention deficit hyperactivity disorder (ADHD).
- Procyclidine, used to relieve tremor. especially in Parkinson's disease. Warfarin or other medicines (called anticoagulants) used to thin the
- Propafenone, flecainide and medicines used to treat irregular heart rate.
- Metoprolol a beta-blocker used to treat high blood pressure and heart problems.
- Pravastatin, used to treat high cholesterol.
- Rifampicin, used to treat tuberculosis (TB) and leprosy. Linezolid, an antibiotic
- Tamoxifen, used to treat breast cancer or fertility problems.

If you are taking or have recently suggest that it is better for you to keep Fertility taken one of the medicines in this taking Parotin list, and you have not yet consulted Make sure that your doctor or with your doctor about them, **ao** midwife knows that you are taking **back to your doctor and ask what Parotin.** If you are taking Parotin near vou should do. The dosage may the end of your pregnancy, there may need to be changed or you may be an increased risk of heavy vaginal need to be given another medicine. bleeding shortly after birth. especially Antidepressants of the **SSRI** and **SNRI** if you have a history of bleeding group could cause serotonin syndrome disorders. Your doctor or midwife (rare) (see in section 2 "Important side should be aware that you are taking effects seen with Parotin" and section 4 Parotin so that they can advise you. "Side effects") When Parotin and similar medicines are taken during pregnancy, particularly The syndrome may occur more frequently if you are taking in the late stages of pregnancy, they concomitantly other medicines which may increase the risk of a serious affect the central nervous system (see condition in babies, called persisten pulmonary hypertension of the above) Inform the doctor about any additional medicine you are taking newborn (PPHN). In this condition, the Use of the medicine and food: blood pressure in the blood vessels Taking Parotin in the morning with food between the baby's heart and lungs is will reduce the likelihood of you feeling too high. nauseous 3 months of pregnancy, your newborn Use of the medicine and alcohol baby might have other medical consumption: conditions, which usually begin during Do not drink alcohol while you are taking Parotin, Alcohol may worser include: your symptoms or side effects. Sleeping difficulties Pregnancy, breastfeeding and Skin that is bluish, or too hot or too fertility: cold If you are pregnant or breastfeeding. Blue lips think you may be pregnant or planning to become pregnant, consult your Vomiting or feeding difficulties Being very tired, difficulty sleeping c doctor or pharmacist before taking this crving a lot medicine. Stiff or floppy muscles Pregnancy In babies whose mothers took Parotin

during the first months of pregnancy. there have been some reports showing an increased risk of birth defects, in particular those affecting the heart. In the general population, about 1 in 100 babies is born with a heart defect In mothers who took Parotin the risk increased to up to 2 out of every 100 babies. You and your doctor may to another treatment or to gradually stop taking Parotin while you are pregnant. However, depending on your circumstances, your doctor may

machinery

- Tremors, nervousness or seizures
- Exaggerated reflexes
- Low blood sugar level

If your baby experiences any of these symptoms at birth, or you are concerned about your baby's health. refer to your doctor for advice.

Breastfeeding

Parotin may pass into breast milk verv small amounts. If you are taking decide that it is better for you to change Parotin, go back and consult with your doctor before you start breastfeeding You and your doctor may decide th you can breastfeed while you are taking Parotin

Animal studies have shown that paroxetine reduces sperm quality. Theoretically, this could affect fertility. but impact on human fertility has not vet been observed.

Driving and operating machinery: Possible side effects of Parotin include dizziness, confusion, feeling sleep or blurred vision. If you develop these side effects, do not drive or operate

3. How should you use

Always use Parotin according to the doctor'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 If you forgot to take the medicine be determined by the doctor only. If you are taking Parotin during the last Sometimes you may need to take more each day than one tablet or take half a tablet. Your doctor will advise you what dosage to take when you first start the first 24 hours after birth. Symptoms taking Parotin. Most people start to feel better after two weeks. Tell vour doctor if you do not start to feel better after this period of time. He may decide to increase the dosage gradually, 10 mg at a time, up to the maximum daily

> Ansane Do not exceed the recommended Method of administration: Take the medicine in the morning with food. Swallow the medicine with water.

ushing/halving/chewing Do not crush or chew. You may halve the tablet to take a partial dosage. Your doctor will tell you how long you will need to keep taking the tablets. The period of taking the medicine may last for many months and even longer. The elderlv

The maximum dosage for people over the age of 65 years is 40 mg per day. Patients with liver or kidney disease If you have liver or kidney problems, your doctor may decide that you need

to take a lower than normal dosage of Parotin. If you have severe liver or kidney disease, the maximum dosage is 20 mg per day. If you accidentally took a higher

Never take more tablets than what your doctor instructs you to take. If you took an overdose or a child accidentally swallowed this medicine ao to the doctor or the emergency room of the hospital immediately and

Anvone who has taken an overdose of Parotin may develop any of the symptoms listed in section 4 "Side effects", or the following symptom: fever or uncontrolled muscle contraction.

Take your medicine at the same time

If you forget a dose, and remember before going to sleep, take it straight away. Continue as usual the next day. If you only remember during the night or the next day, skip the forgotten dose. You may get withdrawal symptoms, but these should go away after you take your next dose at the regular time

Do not take a double dose in order to compensate for a forgotten dose. What to do if your feeling does not improve

Parotin will not relieve your

symptoms straight away - all antidepressants take time to work Some people will start to feel better within two weeks, but for others it may take longer. Some people taking antidepressants feel worse before their feeling improves. If you do not start to feel better after two weeks, go back to vour doctor for advice. Your doctor will ask to see vou again two weeks after vou first start treatment. Tell vour doctor if you have not started to feel better. If you stop taking the medicine Follow the treatment as recommended by the doctor.

Even if there is an improvement in your health do not stop treatment with the medicine without consulting a

When you stop taking Parotin,

vour doctor will help you to reduce the dosage gradually over a number f weeks or months – this may help reduce the chance of withdrawal symptoms. One way of doing this is to gradually reduce the dosage of Parotin you are taking by 10 mg each week. take the package of the medicine with Most people find that the symptoms of stopping Parotin are mild and go away on their own within two weeks. In some people these symptoms can be more severe or last longer.

If you develop withdrawal symptoms

after stopping to take Parotin, your doctor may decide that your treatment should be discontinued more slowly. If you develop severe withdrawal symptoms after stopping to take Parotin, please refer to your doctor. Your doctor may ask you to go back to taking the tablets and then stop the treatment more slowly.

If you do develop withdrawal symptoms, you will still be able to stop taking Parotin. Possible withdrawal symptoms when stopping treatment

Studies show that 3 out of 10 patients experience one or more symptoms after stopping to take Parotin. Some of

the withdrawal symptoms on stopping treatment occur more frequently than others.

Common side effects - side effects that occur in 1-10 out of 100 users:

- Feeling of dizziness, unsteadiness or loss of balance.
- "Pins and needles" sensation. burning sensations and (less commonly) electric current sensations, including in the head.
- Some patients have experienced buzzing, hissing, whistling, ringing or other persistent noise in the ears (tinnitus) when taking Parotin. Sleep disturbances (vivid dreams, nightmares, inability to sleep)

 Feeling of anxiety Headaches

Nausea.

Uncommon side effects - side effects that occur in 1-10 out of 1.000 users:

- Diarrhea (loc
- Sweating stools).
- (including night Feeling emotional of
- sweats). Feeling restless irritable.
- or nervous. Visual disorders
- Tremor. Abnormal
- Feeling heart rate c confused or palpitations. disorientated
- Please refer to your doctor if you are worried about the withdrawal symptoms when stopping Parotin Do not take medicines in the dark! Check the label and the dose eve time you take the medicine. Wear lasses if you need them. f you have any other questions regarding the use of the medicin 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. Side effects are more likely to occur the first few weeks of taking Parotin. Refer to the doctor if you experience any of the following side effects during treatment. You may need to go to a hospital immediately. ncommon side effects - side effects that occur in 1-10 out of .000 users:

- If you have unusual bruising or bleeding, including vomitin blood or passing blood in your stools, refer to your doctor or go to a hospital immediately.
- If you are unable to urinate, refer to your doctor or go to a hospital immediately.

Rare side effects - side effects that occur in 1-10 out of 10.000 users:

- If you experience convulsions (seizures), refer to your doctor or go to a hospital immediately
- If you feel restless and feel that vou cannot sit or stand still. you may have a phenomenon called akathisia. Increasing your dosage of Parotin may worsen these feelings. If you feel like this, refer to your doctor.
- If you feel tired, weak or confused and have achy, stiff or uncoordinated muscles, this may be because your blood sodium level is low. If you experience these symptoms, refer to your doctor. Verv rare side effects - side effects hat occur in less than one out of 10.000 users:
- Allergic reactions to Parotin. which may be severe.

If you develop a red and lumpy skin rash, swelling of the evelids, face, lips, mouth or tongue, start to itch have difficulty breathing (shortness of breath) or swallowing and you feel weakness or dizziness resulting in collapse or loss of consciousness refer to your doctor or go to a hospital immediately.

- If you experience all or some Increa of the following symptoms of ch the blood. you may have a phenomenon called serotonin syndrome of Lack of appetite. neuroleptic malignant syndrome Insomnia or Symptoms include: a strong feeling sleepiness. of nervousness or irritability, a Abnormal dreams • sense of confusion, feeling restless sensation of heat, sweating, tremors, nightmares). chills, hallucinations (strange visions or sounds), muscle stiffness, sudden or unstable muscle spasms or a fast heartbeat. (tremors). If you feel like this, refer to your Headache. doctor Difficulty
- Acute glaucoma. If your eves hurt and you develop blurred vision to your doctor.

Uncommon side effects - side effects that occur in 1-10 out of 1.000 users:

 A brief increase or decrease in blood pressure, which may make you feel dizzv or faint when you stand up suddenly

- A faster than normal heartbeat.
- Lack of movement, stiffness shaking or abnormal movements o the mouth and tongue.
- Dilated pupils
- Skin rashes.
- Itch.
- A sense of confusion
- Having hallucinations (strange visions or sounds).
- An inability to urinate (urinary retention) or an uncontrollable. involuntarv passing of urine (urinarv incontinence).
- If you are a diabetic patient you ma notice a loss of control of your blood sugar levels while taking Parotin. Please talk to your doctor about adjusting your dosage of insulin or diabetes medicines.

Rare side effects - side effects that occur in 1-10 out of 10.000 users:

- Abnormal production of breast milk in men and women
- Slow heartbeat.
- Effects on the liver seen in blood tests of your liver function
- Feeling of anxiety and anxiety attacks
- Overexpression of behavior or thoughts (mania).
- Feeling detached from vourself (depersonalization)
- Irresistible urae to move the leas restless leas syndrome).
- Pain in the joints or muscles.
- Increase in a hormone called prolactin in the blood.
- Menstrual period disorders (including heavy bleeding or irregular periods, bleeding betweer periods and absence or delay of periods).

Verv rare side effects - side effects that occur in less than one out of 10.000 users:

 A skin rash, which may form blisters and look like small targets (central dark spots surrounded by a paler area, with a dark ring around the

edges) called ervthema multiforme

- A widespread rash with blisters and peeling of the skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome).
- A widespread rash with blisters and peeling of the skin over large skin areas (toxic epidermal necrolysis).
- Liver problems that cause vellowing of the skin or the whites of the eves.
- Syndrome of inappropriate antidiuretic hormone secretion (SIADH). A condition in which the body develops an excess of water and a decrease in sodium (salt) concentration, as a result of improper chemical signals. Patients with SIADH may become severely ill or may have no symptoms at all.
- Fluid or water retention (which ma cause swelling of the arms or legs)
- Sensitivity to sunlight.
- Painful erection of the penis that does not do away.
- Low blood platelet count

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

- Inflammation of the intestine (causing diarrhea)
- Teeth arindina.

Some patients have experienced buzzing, hissing, whistling, ringing or other persistent noise in the ears (tinnitus) when taking Parotin. An increased risk of bone fractures has been observed in patients taking this type of medicine.

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.i

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

Do not use the medicine after the expiry date (EXP) appearing on the package. The expiry date refers to the last day of that month.

Storage conditions:

Store in a dry place at a temperature below 25°C. Store in the original package to protect from light

5. Additional information

In addition to the active ingredient, the medicine also contains: Calcium hydrogen phosphate dihvdrate, povidone, starch magnesium stearate, white Opadry OY-S-28917, macrogol 6000 What does the medicine look like and what are the contents of the package 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 marketing authorization holder: CTS Chemical Industries Ltd., P.O. box 385, Kirvat Malachi

This leaflet was revised in April 2023 in accordance with the Ministry of Health auidelines

Registration number of the medicine in the national drug registry of the Ministry of Health: 133-48-31068-00



- An unusual feelina of weakness
- Blurred vision Yawning, drv mouth
- Diarrhea or
- constipation. Vomitina.
- Weight gain.
- Sweating.

- concentrating.

Change in sex drive or sexual function. For example, lack of orgasm, and in men, abnormal

chance of you feeling nauseous

Side effects with unknown

has not vet been determined):

frequency (effects whose frequency

Some people have had thoughts of

harming themselves or committing

suicide while taking Parotin or soon

after stopping treatment (see section

2 "Suicidal thoughts and worsening

of your depression or anxiety

Some people have experienced

aggression while taking Parotin

birth (postpartum hemorrhage)

see "Pregnancy, breastfeeding

Verv common side effects – side

effects that occur in more than one

Nausea. Taking the medicine in the

morning with food will reduce the

and fertility" in section 2 for more

f you experience these side effects.

Heavy vaginal bleeding shortly after

disorder").

information.

out of ten users:

refer to your doctor.

Additional side effects

erection and eiaculation. Common side effects - side effects

cur in 1-10 out	of 100 user
ased levels •	Feeling of
olesterol in	restlessnes