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

Parotin is intended for the treatmen of adults with major/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

Therapeutic class: Selective serotonin reuptake inhibitors (SSRI).

It is not fully understood how Parotin and other selective serotonin reuntake 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

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

- You are sensitive (allergic) t 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 moclobemide 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. meloxicam).
- You are taking an antipsvchotic medicine called thioridazine or an anti-psychot medicine called pimozide.
- the doctor without taking Parotin

use of the medicine: Before treatment with Parotin, tell

- You are taking any other medicines (see in section 2 "Drug
- 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

- You have a family history of QT prolongation, heart diseases such as heart failure, low heart rate or low

 Suicidal thoughts and worsening potassium levels or low magnesium of your depression or anxiety You have epilepsy or you have a
- nistory of seizures or convulsions You have ever had episodes of mania (overactive behavior and
- therapy (ECT)
- you are taking other medicines that may increase the risk of bleeding You may have thoughts of harming about harming yourself or
- You have diabetes.
- ressure). If any of these apply to you, te
- become pregnant (see in section ■ Special warnings regarding the "Pregnancy, breastfeeding and
- interactions").
- You have a kidney. liver or heart

- You are receiving electro-convulsive antidepressants, since all these
- You have a history of bleeding, or
 - (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 is: acetylsalicylic acid, ibuprofen, celecoxib. etodolac. diclofenac.
 - You are on a low sodium diet You have glaucoma (intraocular
 - You are pregnant or planning t
 - 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
- 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

- - If you are depressed and/or have anxiety disorders, you may sometimes have thoughts of harming yourself or

symptoms of sexual dysfunction (see vourself or committing suicide at a

- Certain medicines can affect the way Parotin works, or increase the probability that you will have side effects. Parotin may also affect the way
- taken, other medicines including
- 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 vou have not vet consulted with vour changes in vour behavior doctor about them, go back to your I Important side effects seen with
- doctor and ask what you should do about taking Parotin.

antidepressant. o not use Parotin in children and adolescents under 18 years of age.

- in children under 7 years of age muscle spasms or a fast heartbeat.
- to loss of consciousness. If you notice any of these symptoms, refer to your committing suicide. These thoughts doctor. For more information on these may be increased when first starting or other side effects of Parotin, see section 4 "Side effects". medicines take time to work. Usually Medicines such as Parotin (referred about two weeks, but sometimes even to as selective serotonin reuptake inhibitors, SSRIs) may cause
- You have previously had thoughts
- 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
- vourself or committing suicide. refer to your doctor or go to a hospital immediately
- Some patients who take Parotin Children and adolescents under develop a phenomenon called akathisia, which includes a feeling of restlessness and a feeling as if they cannot sit or stand still
- Parotin is not intended and must not be Other patients develop phenomena 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. following symptoms: a strong feeling of nervousness or irritability, a sense o

- The use of Parotin has not been tested confusion, feeling restless, sensation of heat sweating tremors chills hallucinations (strange visions or sounds), muscle stiffness, sudden
 - There may be aggravation that leads
 - section 4 "Side effects"). In some cases, these symptoms have continued after stopping the treatment. ■ Drug interactions:

inflammation.

Tramadol, buprenorphine and

pethidine – pain relievers.

- certain other medicines work. If you are taking, or have recently
- If you have thoughts of harming 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 Propafenone, flecainide and activity (such as the anti-psychotic medicines thioridazine and pimozide) – see in section 2 "Do not • Metoprolol – a beta-blocker used use this medicine if
 - Acetylsalicylic acid (aspirin) heart problems. ibuprofen or other medicines called NSAIDs (non-steroidal cholesterol. anti-inflammatory drugs) such as celecoxib, etodolac, diclofenac and meloxicam, used to treat pain and
 - Tamoxifen, used to treat breast

- Buprenorphine in combination with naloxone – an alternative treatment taken one of the medicines in this taking Parotin for opioid addiction. Medicines called *triptans*, such as with your doctor about them. **qo** sumatriptan, used to treat migrain
- Other antidepressants including **vou should do.** The dosage may need to be changed or you may SSRIs, tryptophan and tricyclic antidepressants such as clomipramine, nortriptyline and
- A nutritional supplement called tryptophan. Mivacurium and suxamethonium "Side effects")

desipramine.

(used in anesthesia)

Medicines such as lithium.

the treatment of chronic pain.

- risperidone, perphenazine, clozapine certain **psychiatric conditions**. Fentanyl for use in anesthesia or for
- A combination of fosamprenavir and ritonavir. used to treat human immunodeficiency virus (HIV)
- Hypericum (St. John's wort), an herbal remedy for depression phenobarbital, phenytoin, sodium
- valproate or carbamazepine, used to vour symptoms or side effects. treat seizures or epilepsy. Atomoxetine, used to treat attention
- deficit hyperactivity disorder If you are pregnant or breastfeeding. think you may be pregnant or planning Procyclidine, used to relieve tremor. to become pregnant, consult your doctor or pharmacist before taking this

during the first months of pregnancy.

100 babies is born with a heart defect

In mothers who took Parotin the risk

increased to up to 2 out of every 100

to another treatment or to gradually

pregnant. However, depending on your

babies. You and your doctor may

stop taking Parotin while you are

circumstances, your doctor may

- especially in Parkinson's disease. Warfarin or other medicines (called medicine. anticoagulants) used to thin the In babies whose mothers took Parotin
- medicines used to treat irregular there have been some reports showing an increased risk of birth defects, in particular those affecting the heart. to treat high blood pressure and In the general population, about 1 in
- Pravastatin, used to treat high Rifampicin, used to treat tuberculosis (TB) and leprosy. Linezolid, an antibiotic
 - cancer or fertility problems.

- If you are taking or have recently suggest that it is better for you to keep Fertility list, and you have not yet consulted Make sure that your doctor or midwife knows that you are taking **back to your doctor and ask what Parotin.** If you are taking Parotin near the end of your pregnancy, there 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 vou.

When Parotin and similar medicines

between the baby's heart and lungs is

3 months of pregnancy, your newborn

very small amounts. If you are taking

- 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 persistent 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 will reduce the likelihood of you feeling too high. ■ Use of the medicine and alcohol

The syndrome may occur more

- baby might have other medical conditions, which usually begin during Do not drink alcohol while you are taking Parotin, Alcohol may worser include:
- Sleeping difficulties ■ Pregnancy, breastfeeding and Skin that is bluish, or too hot or too
 - Vomiting or feeding difficulties Being very tired, difficulty sleeping of crying a lot
 - Stiff or floppy muscles Method of administration: Take the
 - medicine in the morning with food. Tremors, nervousness or seizures Swallow the medicine with water. Exaggerated reflexes Low blood sugar level ushing/halving/chewing
 - If your baby experiences any of Do not crush or chew. You may halve these symptoms at birth, or you are the tablet to take a partial dosage. concerned about your baby's health. Your doctor will tell you how long you refer to your doctor for advice. will need to keep taking the tablets. The period of taking the medicine may Parotin may pass into breast milk
- decide that it is better for you to change Parotin, go back and consult with your doctor before you start breastfeeding the age of 65 years is 40 mg per day. You and your doctor may decide that you can breastfeed while you are 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 Animal studies have shown that paroxetine reduces sperm quality. Theoretically, this could affect fertility. is 20 mg per day. but impact on human fertility has not If you accidentally took a higher vet been observed. ■ Driving and operating machinery:

Possible side effects of Parotin include

dizziness, confusion, feeling sleepy

side effects, do not drive or operate

3. How should you use

or blurred vision. If you develop these

Never take more tablets than what your doctor instructs you to take. If you took an overdose or a child accidentally swallowed this medicine go to the doctor or the emergency room of the hospital immediately and Anyone who has taken an overdose of Parotin may develop any of the

Always use Parotin according to the doctor's instructions. Check with symptoms listed in section 4 "Side the doctor or pharmacist if you are effects", or the following symptoms uncertain about the dosage and how to fever or uncontrolled muscle

The dosage and treatment regimen will If you forgot to take the medicine be determined by the doctor only. Take your medicine at the same time 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. If you forget a dose, and remember before going to sleep, take it straight Your doctor will advise you what

dosage to take when you first start away. Continue as usual the next day. the first 24 hours after birth. Symptoms taking Parotin. Most people start to If you only remember during the feel better after two weeks. Tell vour **night or the next day.** skip the doctor if you do not start to feel better forgotten dose. You may get withdrawal after this period of time. He may decide symptoms, but these should go away to increase the dosage gradually, 10 after you take your next dose at the mg at a time, up to the maximum daily

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

by the doctor.

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

last for many months and even longer. your doctor for advice. Your doctor will The maximum dosage for people over ask to see you again two weeks after vou first start treatment. Tell your doctor if you have not started to feel better. Patients with liver or kidney disease If you stop taking the medicine

health do not stop treatment with kidney disease, the maximum dosage the medicine without consulting a When you stop taking Parotin, vour doctor will help you to reduce

Feeling of anxiety

Uncommon side effects - side

effects that occur in 1-10 out of

(including night • Feeling

Diarrhea (loc

stools).

irritable.

Abnormal

Please refer to your doctor if you

any of the following side effects

effects that occur in 1-10 out of

to your doctor or go to a hospital

.000 users:

immediately.

emotional of

Visual disorders

heart rate of

palpitations.

Headaches

1.000 users:

sweats).

or nervous.

confused or

Nausea. 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 Feeling restless gradually reduce the dosage of Parotin you are taking by 10 mg each week. Tremor. 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.

are worried about the withdrawal If you develop withdrawal symptoms symptoms when stopping Parotin after stopping to take Parotin, your Do not take medicines in the dark! doctor may decide that your treatmen Check the label and the dose eve should be discontinued more slowly. time you take the medicine. Wear If you develop severe withdrawal lasses if you need them. symptoms after stopping to take fyou have any other questions Parotin, please refer to your doctor. regarding the use of the medicin Your doctor may ask you to go back consult the doctor or the to taking the tablets and then stop the pharmacist. treatment more slowly.

If you do develop withdrawal 4. Side effects symptoms, you will still be able to As with any medicine, using Parotin stop taking Parotin. may cause side effects in some users Possible withdrawal symptoms Do not be alarmed when reading

when stopping treatment the list of side effects. You may not Studies show that 3 out of 10 patients experience any of them. experience one or more symptoms Side effects are more likely to occur after stopping to take Parotin. Some of the first few weeks of taking Parotin. the withdrawal symptoms on stopping Refer to the doctor if you experience

during treatment. You may need to go Common side effects - side effects to a hospital immediately. that occur in 1-10 out of 100 users: ncommon side effects - side

Feeling of dizziness, unsteadiness or loss of balance.

treatment occur more frequently than

- "Pins and needles" sensation. · If you have unusual bruising burning sensations and (less or bleeding, including vomitin commonly) electric current blood or passing blood in your sensations, including in the head. stools, refer to your doctor or go Some patients have experienced to a hospital immediately. If you are unable to urinate, refer
- buzzing, hissing, whistling, ringing or other persistent noise in the ears (tinnitus) when taking Parotin. Sleep disturbances (vivid dreams, Follow the treatment as recommended
 - nightmares, inability to sleep)

occur in 1-10 out of 10,000 users: If you experience convulsions

Rare side effects - side effects that

If you feel tired, weak or

confused and have achy, stiff

or uncoordinated muscles, this

symptoms, refer to your doctor.

Very rare side effects - side effects

that occur in less than one out of

Allergic reactions to Parotin.

which may be severe.

hospital immediately.

10.000 users:

may be because your blood sodium

level is low. If you experience these

If you develop a red and lumpy skin

rash, swelling of the eyelids, face.

lips, mouth or tongue, start to itch

have difficulty breathing (shortness

weakness or dizziness resulting in

collapse or loss of consciousness

refer to your doctor or go to a

If you experience all or some

of the following symptoms

you may have a phenomenor

called **serotonin syndrome** of

of nervousness or irritability, a

neuroleptic malignant syndrome

Symptoms include: a strong feeling

sense of confusion, feeling restless

sensation of heat, sweating, tremors.

chills, hallucinations (strange visions

or sounds), muscle stiffness, sudden

muscle spasms or a fast heartbeat.

If you feel like this, refer to your

Acute glaucoma. If your eyes hurt

of breath) or swallowing and you feel

frequency (effects whose frequency has not yet been determined): (seizures), refer to your doctor or Some people have had thoughts of go to a hospital immediately

refer to your doctor.

out of ten users:

Additional side effects

Very common side effects - side

effects that occur in more than one

Nausea. Taking the medicine in the

morning with food will reduce the

chance of you feeling nauseous

Change in sex drive or sexual

function. For example, lack of

erection and eiaculation.

of cholesterol in

Lack of appetite.

the blood.

Insomnia or

nightmares).

or unstable

concentrating.

Uncommon side effects - side

effects that occur in 1-10 out of

(tremors).

Headache.

Difficulty

1.000 users:

sleepiness.

orgasm, and in men, abnormal

that occur in 1-10 out of 100 users

Blurred vision

Diarrhea or

Vomiting.

Sweating.

Weight gain.

Yawning, dry

Increased levels • Feeling of

harming themselves or committing If you feel restless and feel that suicide while taking Parotin or soon vou cannot sit or stand still. you after stopping treatment (see section may have a phenomenon called 2 "Suicidal thoughts and worsening akathisia. Increasing your dosage of of your depression or anxiety Parotin may worsen these feelings. If you feel like this, refer to your Some people have experienced

Side effects with unknown

- Having hallucinations (strange aggression while taking Parotin visions or sounds). Heavy vaginal bleeding shortly after An inability to urinate (urinary
- birth (postpartum hemorrhage) retention) or an uncontrollable. see "Pregnancy, breastfeeding involuntary passing of urine (urinary and fertility" in section 2 for more incontinence). If you are a diabetic patient you ma f you experience these side effects. 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.

dizzy or faint when you stand up

shaking or abnormal movements o

Lack of movement, stiffness

the mouth and tongue.

A sense of confusion

Skin rashes.

Itch.

- occur in 1-10 out of 10.000 users: Abnormal production of breast milk
- Slow heartbeat.
- Effects on the liver seen in blood tests of your liver function
- Feeling of anxiety and anxiety
- Common side effects side effects Overexpression of behavior or
 - houghts (mania). Feeling detached from yourself
 - (depersonalization) Irresistible urge to move the legs 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
 - Very 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 A brief increase or decrease in blood area, with a dark ring around the

 A widespread rash with blisters A faster than normal heartbeat.

and peeling of the skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome).

edges) called ervthema multiforme

- 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) Rare side effects - side effects that Sensitivity to sunlight.
 - Painful erection of the penis tha does not go away.
- Low blood platelet count in men and women Side effects with unknown
 - frequency (effects whose frequency
 - Inflammation of the intestine
 - (causing diarrhea)
 - Teeth arinding. Some patients have experienced

type of medicine.

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

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 If a side effect occurs, if one of the

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

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

5. How to store the medicine

Avoid poisoning! This medicine and

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.

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

Storage conditions:

In addition to the active ingredient, the medicine also contains: Calcium hydrogen phosphate

dihydrate, povidone, starch magnesium stearate, white Opadr\ 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 10. 15. 20. 30. 50 or 60 tablets in a

package. Not all package sizes may be

Manufacturer and marketing authorization holder: CTS Chemical Industries Ltd., P.O. box 385, Kirvat

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

Registration number of the medicine in the national drug registry of the Ministry side effects worsens, or if you suffer