

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

The medicine is dispensed with a doctor's prescription only

Parotin 20 mg film-coated tablets

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

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 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 intended for?

Parotin is intended for the treatment 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 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 you feel better.

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

- You are **sensitive (allergic)** to paroxetine or to any of the other ingredients this medicine contains (for the list of inactive ingredients see section 6).
- You are taking medicines called **monoamine oxidase inhibitors** (MAOIs, including moclobemide and methylthionium chloride (methylene blue)) or if you have been taking them in the past two weeks. Your doctor will advise you how you should begin taking Parotin once you stop taking monoamine oxidase inhibitors.
- You are taking an **anti-psychotic medicine** called thionidazine or an anti-psychotic medicine called pimozide.
- **If any of these apply to you,** tell 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 problem.
- An abnormality known as QT interval prolongation has been found in the results of the cardiac ECG follow-up test.

- You have a family history of QT prolongation, heart diseases such as heart failure, low heart rate or low potassium levels or low magnesium levels.
- You have epilepsy or you have a history of seizures or convulsions.
- You have ever had episodes of mania (overactive behavior and thoughts).
- You are receiving electro-convulsive 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 called non-steroidal anti-inflammatory drugs (NSAIDs) such as: 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 to become pregnant (see in section 2 "Pregnancy, breastfeeding and fertility").
- 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 yet consulted with your doctor about them, go back to your doctor and ask what you should do about taking Parotin.**

Children and adolescents under the age of 18: Do not use Parotin in children and adolescents under 18 years of age.

Parotin is not intended and must not be used to treat children and adolescents, since clinical studies have found a link between Parotin and an increased risk of suicidal and hostile behavior.

The use of Parotin has not been tested in children under 7 years of age.

Suicidal thoughts and worsening of your depression or anxiety 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 antidepressants, since all these medicines take time to work. Usually about two weeks, but sometimes even longer.

You may have thoughts of harming yourself or committing suicide at a higher probability if:

- You have previously had thoughts about harming yourself or committing suicide.
- You are a **young 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 yourself 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 changes in your behavior.

Important side effects seen with Parotin:

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.**

Other patients develop phenomena called **serotonin syndrome, or neuroleptic malignant syndrome,** which include some or all of the following symptoms: a strong feeling of nervousness or irritability, a 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. 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 methylthionium 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 **anti-psychotic** 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 **migraine.**
- Other **antidepressants** including SSRIs, tryptophan and tricyclic antidepressants such as clomipramine, nortriptyline and desipramine.
- A **nutritional supplement** called tryptophan.
- 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).**
- Prochloridone, used to relieve tremor, especially in **Parkinson's disease.**
- Warfarin or other medicines (called *anticoagulants*) used to **thin the blood.**
- 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.**

suggest that it is better for you to keep taking Parotin.

Make sure that your doctor or midwife knows that you are taking Parotin. If you are taking Parotin near the end of your pregnancy, there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking Parotin so that they can advise you. When Parotin and similar medicines are taken during pregnancy, particularly in the late stages of pregnancy, they may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN). In this condition, the blood pressure in the blood vessels between the baby's heart and lungs is too high.

If you are taking Parotin during the last 3 months of pregnancy, your newborn baby might have other medical conditions, which usually begin during the first 24 hours after birth. Symptoms include:

- Sleeping difficulties
- Skin that is bluish, or too hot or too cold
- Blue lips
- Vomiting or feeding difficulties
- Being very tired, difficulty sleeping or crying a lot
- Stiff or floppy muscles
- 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 in very small amounts. If you are taking Parotin, go back and consult with your doctor before you start breastfeeding. You and your doctor may decide that you can breastfeed while you are taking Parotin.

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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).

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

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

3. How should you use Parotin?

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 be determined by the doctor only. Sometimes you may need to take more than one tablet or take half a tablet.

Your doctor will advise you what dosage to take when you first start taking Parotin. Most people start to feel better after two weeks. Tell your 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 dosage.

Do not exceed the recommended dose. **Method of administration:** Take the medicine in the morning with food. Swallow the medicine with water. **Crushing/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 elderly 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 dosage** **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 take the package of the medicine with you.

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

If you forgot to take the medicine Take your medicine at the same time each day. **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 your doctor for advice. Your doctor will ask to see you again two weeks after you first start treatment. Tell your 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 doctor.** **When you stop taking Parotin,** your doctor will help you to reduce the dosage gradually over a number of 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. 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.

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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).

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