



GENERIC NAME: paroxetine

DRUG CLASS AND MECHANISM

Paroxetine is an oral drug that is used for treating depression. It is in a class of drugs called selective serotonin reuptake inhibitors (SSRIs), a class that also contains fluoxetine (Prozac), citalopram (Celexa), and sertraline (Zoloft). Paroxetine affects neurotransmitters, the chemicals that nerves within the brain use to communicate with each other. Neurotransmitters are manufactured and released by nerves and then travel and attach to nearby nerves. Thus, neurotransmitters can be thought of as the communication system of the brain. Serotonin is one neurotransmitter that is released by nerves in the brain. The serotonin either travels across the space that lies between nerves and attaches to receptors on the surface of nearby nerves or it attaches to receptors on the surface of the nerve that produced it, to be taken up by the nerve and released again (a process referred to as reuptake).

Many experts believe that an imbalance among neurotransmitters is the cause of depression. Paroxetine works by preventing the reuptake of one neurotransmitter, serotonin, by nerve cells after it has been released. Since reuptake is an important mechanism for removing released neurotransmitters and terminating their actions on adjacent nerves, the reduced uptake caused by paroxetine increases free serotonin that stimulates nerve cells in the brain. The FDA approved paroxetine in December 1992.

PRESCRIPTION: Yes

GENERIC AVAILABLE: Yes

PREPARATIONS: Tablets: 10, 20, 30, and 40 mg; Paxil CR Tablets: 12.5, 25,

and 37.5 mg; Suspension: 10 mg/5ml

Paroxetine is used for the management of depression, obsessivecompulsive disorders (OCD), panic disorders, post traumatic stress disorder (PTSD), premenstrual dysphoric disorder (PMDD), and social anxiety disorder

The recommended dose is 20-60 mg daily of immediate release tablets or 12.5-75 mg daily using controlled release tablets. Paroxetine is given as a single daily dose, usually in the morning. As with all anti-depressants, the full effect may not occur until after a few weeks of therapy. Doses for obsessivecompulsive disorders and panic disorders are often higher than those for depression. Doses often are adjusted to find the optimal dose. Elderly patients, debilitated persons, and patients with certain kidney or liver diseases may need lower doses because they metabolize and eliminate paroxetine more slowly and, therefore, are prone to develop high blood levels and toxicity.

DRUG INTERACTIONS

All SSRIs, including paroxetine, should not be taken with any of the monoamine oxidase inhibitor (MAOI) class of antidepressants, for example, isocarboxazid (Marplan), phenelzine (Nardil), tranylcypromine (Parnate), selegiline (Eldepryl, Carbex), and procarbazine (Matulane) or other drugs that inhibit monoamine oxidase, for example, linezolid (Zyvox). Such combinations may lead to confusion, high blood pressure, tremor, hyperactivity, coma, and death. (A period of 14 days without treatment should lapse when switching between paroxetine and MAOIs.) Similar reactions occur when paroxetine is combined with other drugs [for example, tryptophan, St. John's wort, meperidine (Demerol), tramadol (Ultram) that increase serotonin in the brain.

USES

This medication is a selective serotonin reuptake inhibitor (SSRI) used to treat depression, panic attacks, obsessive-compulsive disorder (OCD), social anxiety disorder (social phobia), post-traumatic stress disorder (PTSD), and generalized anxiety disorders (GAD). Paroxetine should not be used in children less than 18 years of age. It has not been shown to be effective for depression in children or teenagers. It may also cause serious side effects in this age group (see Side Effects section). Consult your doctor or pharmacist for more details. SSRI's work by helping to restore the balance of certain natural substances in the brain (neurotransmitters).

OTHER USES

This medication has also been used to treat a severe form of premenstrual syndrome (premenstrual dysphoric disorder- PMDD), sexual function problems in men (premature ejaculation), nerve problems associated with diabetes (diabetic neuropathy), and chronic headaches.

HOW TO USE

Take this medication by mouth usually once daily in the morning, with or without food; or as directed by your doctor. The dosage is based on your medical condition and response to therapy. It is important to continue taking this medication as prescribed even if you feel well. Do not stop taking this medication without consulting your doctor. Some conditions may become worse when the drug is abruptly stopped. Your dose may need to be gradually decreased. It may take up to several weeks before the full benefit of this drug takes effect.

SIDE EFFECTS

Nausea, vomiting, drowsiness, dizziness, diarrhea, trouble sleeping, yawning, constipation, or dry mouth may occur. If any of these effects persist or worsen, notify your doctor promptly. Tell your doctor immediately if any of these serious side effects occur: loss of appetite, unusual or severe mental/mood changes, increased sweating/flushing, unusual fatigue, uncontrolled movements (tremor), decreased interest in sex, changes in sexual ability. Tell your doctor immediately if any of these unlikely but serious side effects occur: black stools, blurred vision, change in amount of urine, "coffee ground" vomit, easy bruising/bleeding. Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: fainting, irregular heartbeat, muscle pain, trouble swallowing, unusual swelling, seizures, tingling or numbness of the hands/feet. Paroxetine may infrequently cause suicidal thoughts or self-harm urges in children or teenagers up to 18 years of age. Tell the doctor immediately should this occur (see Uses section). Males: In the very unlikely event you have a painful, prolonged erection, stop using this drug and seek immediate medical attention or permanent problems could occur. A serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, itching, swelling, severe dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS

Before taking paroxetine, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. Before using this medication, tell your doctor or pharmacist your medical history, especially of: liver problems, kidney problems, seizures, heart problems, stomach ulcers, glaucoma (narrow angle type), other mental/mood disorders (e.g., bipolar disorder), thyroid problems. This drug may make you dizzy or drowsy; use caution engaging in activities requiring alertness such as driving or using machinery. Avoid alcoholic beverages. Though uncommon, depression can lead to thoughts or attempts of suicide. Tell your doctor immediately if you have any suicidal thoughts, worsening depression, or any other mental/mood changes (including new or worsening anxiety, agitation, panic attacks, trouble sleeping, irritability, hostile/angry feelings, impulsive actions, severe restlessness, rapid speech). Keep all medical appointments so your healthcare professional can monitor your progress closely and adjust/change your medication if needed. Caution is advised when using this product in the elderly because they may be more sensitive to its effects. The elderly are more likely to develop a type of electrolyte imbalance (hyponatremia), especially if they are also taking "water pills" or diuretics with this medication. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. If this medication is used during the last 3 months of pregnancy, infrequently your newborn may develop symptoms including feeding or breathing difficulties, seizures, muscle stiffness, jitteriness, or constant crying. However, do not stop taking this medication unless your doctor directs you to do so. Report any such symptoms to your doctor promptly. This drug passes into breast milk. Because of the potential risk to the infant, breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding.

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include: irregular heartbeat, fainting, severe dizziness, lightheadedness, or seizures.

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Store at room temperature between 59-86 degrees F (15-30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.

Note: This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of -from the most common to the most challenging—for people around conditionsthe world.



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Taj Pharmaceuticals Ltd.

Phone : General EPA BX : 91 - (0)22 - 26374592/92 91, (0)22 - 26374592/93 91 - (0)22 - 30601000,

Fax: 91-(0)22-26341274