

Paraxyl[®] 20 mg TABLET (PAROXETINE)

پراکسیل

COMPOSITION

Each film coated tablet contains:
Paroxetine as HCl (USP) 20 mg.

Product Specs.: USP

DESCRIPTION: PARAXYL (paroxetine hydrochloride) is an orally administered psychotropic drug.

CLINICAL PHARMACOLOGY:

Mechanism of Action: An SSRI that enhances CNS serotonin by inhibiting reuptake, with low receptor affinity, minimizing anticholinergic, sedative, and cardiovascular side effects.

Pharmacokinetics:

Absorption & Distribution: Completely absorbed orally; widely distributed in the body including the CNS; ~95% protein bound.

Metabolism: Primarily metabolized by CYP2D6; metabolites excreted mainly in urine, partly in feces.

Excretion: After a 30 mg oral dose, ~64% excreted in urine (2% unchanged, 62% metabolites) and ~36% in feces (<1% unchanged).

Special populations: Renal or hepatic impairment increases plasma concentrations two-fold; use lower initial doses and titrate cautiously.

INDICATIONS AND USAGE:

PARAXYL is indicated for the treatment of:

- Major Depressive Disorder | obsessive compulsive disorder (OCD) | Social Anxiety Disorder (Social Phobia) | Generalized Anxiety Disorder (GAD) | Posttraumatic Stress Disorder (PTSD)

DOSAGE AND ADMINISTRATION:

Indication	Initial	Titration	Maintenance
Major Depressive Disorder (MDD)	20 mg once daily (morning, with/without food)	Increase by 10 mg/week if needed; max 50 mg/day	Continue for several months or longer; efficacy shown up to 1 year (avg. 30 mg/day)
Obsessive Compulsive Disorder (OCD)	20 mg/day; titrate by 10 mg/week	40 mg/day; max 60 mg/day	Continue long-term if effective; use lowest effective dose
Panic Disorder (PD)	10 mg/day; titrate by 10 mg/week	40 mg/day; max 60 mg/day	Continue long-term if effective; adjust to lowest effective dose
Social Anxiety Disorder (SAD)	20 mg/day	40 mg/day; max 60 mg/day	Continue in responders; reassess periodically
Generalized Anxiety Disorder (GAD)	20 mg/day	May increase in 10 mg/week increments if needed	Periodic reassessment recommended.
Posttraumatic Stress Disorder (PTSD)	20 mg/day	Increase in 10 mg/week increments if needed	Continue long-term in responders; use lowest effective dose

DOSE MODIFICATION RECOMMENDATIONS:

Pregnancy: Use only after careful risk–benefit assessment.

Elderly, debilitated, severe renal/hepatic impairment: Start at 10 mg/day; titrate cautiously. Max 40 mg/day.

CONTRAINDICATIONS:

- Concomitant use with MAOIs, or within 14 days of stopping PARAXYL or an MAOI (risk of serotonin syndrome).
- Use with linezolid or IV methylene blue.
- Use with thioridazine or pimozide.
- Known hypersensitivity to paroxetine.

WARNINGS AND PRECAUTION:

- Suicidality:** Risk increases early in treatment or with dose changes; monitor closely. Taper to avoid withdrawal.
- Bipolar:** Screen before use; monotherapy may trigger mania or mixed episodes.
- MAOIs:** Contraindicated due to risk of severe, potentially fatal reactions.
- Serotonin Syndrome/NMS:** Risk with serotonergic or antidopaminergic drugs; discontinue if suspected.
- QT Prolongation:** Contraindicated with thioridazine due to torsades risk

DRUG INTERACTIONS:

Contraindicated: Pimozide, Thioridazine – Risk of QT prolongation and serious arrhythmias.

Tryptophan – Not recommended due to risk of serotonin syndrome.

Use with Caution (Serotonin Syndrome Risk): Other serotonergic drugs – e.g., triptans, lithium, fentanyl, tramadol, amphetamines, St. John's Wort.

Triptans – Monitor closely, especially at initiation or dose increase.

Lithium – No PK interaction, but risk of serotonin syndrome.

CYP-Mediated Interactions: CYP2D6 substrates/inhibitors (TCAs, fluoxetine, phenothiazines, risperidone, Type 1C antiarrhythmics, quinidine) – Use caution.

Tamoxifen – Paroxetine may reduce efficacy by inhibiting CYP2D6.

Cimetidine – May increase paroxetine levels; adjust dose by clinical effect.

Phenobarbital/Phenytoin – No initial adjustment, but monitor.

Other Drug Classes: Warfarin, NSAIDs, Aspirin – Increased bleeding risk; monitor closely.

Plasma protein–bound drugs – Possible displacement interactions.

Digoxin – Use with caution.

Diazepam – No effect noted.

Procyclidine – Reduce dose if anticholinergic effects occur.

Theophylline – Monitor drug levels.

Fosamprenavir/Ritonavir – May lower paroxetine levels; adjust by clinical effect.

Other Considerations: Alcohol – Advise avoidance despite no added impairment.

ADVERSE REACTIONS:

Nausea, dry mouth, sweating, asthenia, somnolence, dizziness, insomnia, tremor, constipation, diarrhea, decreased appetite, decreased libido, abnormal ejaculation, impotence, female genital disorders, weight changes, allergic reactions, edema, malaise, chills, neck pain, hypertension, tachycardia, bradycardia, hypotension, migraine, syncope, hematoma, increased LFTs, thirst, arthralgia, arthritis, arthrosis, emotional lability, vertigo, hallucinations, euphoria, hostility, mania, ataxia, dystonia, dyskinesia, paranoia, pruritus, rash, alopecia, urticaria, eczema, photosensitivity, and ecchymosis.

DRUG ABUSE AND DEPENDENCE:

Physical and Psychologic Dependence: Observe closely for signs of misuse or abuse of PARAXYL (e.g., development of tolerance, increments of dose, drug-seeking behavior).

OVERDOSAGE:

No specific antidote available. Provide general supportive and symptomatic care. Do not induce emesis. Due to large volume of distribution, forced diuresis, dialysis, hemoperfusion, or exchange transfusion unlikely to be beneficial. Prolonged monitoring may be needed if drug accumulation occurs.

USE IN SPECIFIC POPULATIONS:

Pregnancy (Category D): Advise patients to inform physician if pregnant or planning pregnancy during therapy.

Nursing mothers: Advise patients to inform physician if breastfeeding.

Pediatric use: Safety and effectiveness not established. Risks vs. benefits must be weighed carefully.

Geriatric use: Elderly patients have increased risk of clinically significant hyponatremia with SSRIs/SNRIs.

INSTRUCTIONS:

Store below 30°C. Protect from heat, sunlight & moisture. Keep out of the reach of children. For adults above 18 years only.

To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:

Paraxyl Tablet 20 mg : Pack of 1 x 10 tablets.

Manufactured by:
CCL Pharmaceuticals (Pvt.) Ltd.
Plot No. 710, Sundar Industrial Estate, Raiwind Road Lahore, Pakistan.

FOR FURTHER INFORMATION PLEASE CONTACT:



Manufactured for:
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ہدایات:

۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

گرمی، دھوپ اور نمی سے بچائیں۔

بچوں کی پہنچ سے دور رکھیں۔

صرف ۱۸ سال سے زائد عمر افراد کیلئے۔

صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔