Summary of prescribing information for PEXEP CR tablets

Active Ingredient: Each film-coated controlled-release tablet of PEXEP CR contains: Paroxetine hydrochloride eq. to Paroxetine 12.5mg, 25mg, 37.5mg. **Indication:** in adults for the treatment of: Major Depressive Disorder (MDD), Panic Disorder (PD). **Dosage:** Swallow tablet whole; do not chew or crush. MDD: Starting Dose – 25 mg/day Maximum Dose – 62.5 mg/day. PD: Starting Dose – 12.5 mg/day Maximum Dose – 75 mg/day**.** If inadequate response to starting dosage, titrate in 12.5 mg per day increments once weekly. Elderly patients, patients with severe renal impairment or severe hepatic impairment: Starting dose is 12.5 mg per day. Do not exceed 50 mg per day. When discontinuing, reduce dose gradually. **Contraindications:** Concomitant use in patients taking either monoamine oxidase inhibitors (MAOIs), pimozide or thioridazine, patients with a hypersensitivity to paroxetine or to any ingredients of formulations. **Warning and precautions:** clinical worsening and emergence of suicidal thoughts. Serotonin Syndrome: Increased risk when co-administered with other serotonergic agents (e.g., SSRI, SNRI, triptans), but also when taken alone. Embryofetal and Neonatal Toxicity: Can cause fetal and neonatal harm. Increased risk of cardiovascular malformations for exposure during the first trimester. Exposure in late pregnancy may lead to an increased risk for persistent pulmonary hypertension (PPNH) of the newborn. Increased Risk of Bleeding: Concomitant use of aspirin, nonsteroidal antiinflammatory drugs, other antiplatelet drugs, warfarin, and other anticoagulant drugs may increase risk. Activation of Mania/Hypomania: Screen patients for bipolar disorder. Seizures: Use with caution in patients with seizure disorders. Angle-Closure Glaucoma: has occurred in patients with untreated anatomically narrow angles treated with antidepressants. **Pregnancy & Lactation:** Use in pregnant women is not recommended. Breast-feeding should be avoided when administered to a nursing woman. **Interaction:** Drugs Highly Bound to Plasma Protein: Monitor for adverse reactions and reduce dosage of paroxetine or other protein-bound drugs (e.g., warfarin) as warranted. Drugs Metabolized by CYP2D6: Reduce dosage of drugs metabolized by CYP2D6 as warranted. Concomitant use with Tamoxifen: Consider use of an alternative antidepressant with little or no CYP2D6 inhibition. **Adverse reactions:** Common headache, asthenia, abnormal ejaculation, abnormal vision, constipation, decreased appetite, diarrhea, dizziness, dry mouth, female genital disorder, impotence, insomnia, libido decreased, nausea, somnolence, sweating, tremor. **Overdose:** symptoms include somnolence, coma, nausea, tremor, tachycardia, confusion, vomiting, and dizziness. Mydriasis, convulsions (including status epilepticus), ventricular dysrhythmias (including torsade de pointes), hypertension, aggressive reactions, syncope, hypotension, stupor, bradycardia, dystonia, rhabdomyolysis, symptoms of hepatic dysfunction (including hepatic failure, hepatic necrosis, jaundice, hepatitis, and hepatic steatosis), serotonin syndrome, manic reactions, myoclonus, acute renal failure, and urinary retention also reported. Overdose Management: No specific antidotes for paroxetine are known.

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It is recommended to refer full prescribing information before prescription.

For further medical information, please write to: Intas Pharmaceuticals Ltd., Corporate House, Near Sola Bridge, SG highway, Thaltej, Ahmedabad-380054, Gujarat, India. productqueries@intaspharma.com