Summary of prescribing information for PEXEP tablets

Active Ingredient: Each film coated tablet of PEXEP contains: Paroxetine hydrochloride eq. to Paroxetine 10mg, 20mg, 30mg, 40mg. **Indication:** for major depression, obsessive compulsive disorders and panic disorders. **Dosage:** should be administered as a single daily dose with or without food, usually in the morning. Major Depressive Disorder: Usual Initial Dosage: Recommended initial dose 20 mg/day. Patients not responding to a 20-mg dose may benefit from dose increases, in 10-mg/day increments, up to a maximum of 50 mg/day. Dose changes should occur at intervals of at least 1 week. Maintenance Therapy: acute episodes of major depressive disorder require several months or longer of sustained pharmacologic therapy. Whether the dose needed to induce remission is identical to the dose needed to maintain and/or sustain euthymia is unknown. Obsessive Compulsive Disorder: Usual Initial Dosage: recommended dose 40 mg daily. Patients should be started on 20 mg/day and the dose can be increased in 10-mg/day increments at intervals of at least 1 week. The maximum dosage should not exceed 60 mg/day. Panic Disorder: target dose 40 mg/day. Patients should be started on 10 mg/day. Dose can be increased in 10-mg/day increments at intervals of at least 1 week. Maximum dosage should not exceed 60 mg/day. **Contraindications:** Concomitant use in patients taking either monoamine oxidase inhibitors (MAOIs) or thioridazine, patients with a hypersensitivity to paroxetine or to any ingredients of formulations. **Warning and precautions:** Clinical Worsening and Suicide Risk. Potential for Interaction with MAOIs: should not be used in combination with a MAOI, or within 14 days of discontinuing treatment with a MAOI. History of Mania: should be used with caution in patients with a history of mania. Patients Receiving Oral Anticoagulants. Discontinuation of treatment or slowly taper-off. Seizures: should be used cautiously in patients with a history of seizures, discontinued in any patient who develops seizures. **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.

Prepared on 24th Feb 2020.

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