PARADISE XR

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory.

Abbreviated Prescribing information for PARADISE XR **(Paroxetine Extended-Release 12.5 mg Tablets U.S.P.)** [Please refer the complete prescribing information available at www.torrentpharma.com] **PHARMACOLOGICAL PROPERTIES**: The efficacy of Paroxetine in the treatment of major depressive disorder, panic disorder, social anxiety disorder, and premenstrual dysphoric disorder (PMDD) is presumed to be linked to potentiation of serotonergic activity in the central nervous system resulting from inhibition of neuronal reuptake of serotonin (5-hydroxy-tryptamine, 5-HT). **INDICATIONS**: Major depressive disorder, panic disorder, social anxiety disorder and premenstrual dysphoric disorder **DOSAGE AND ADMINISTRATION**: **Major Depressive Disorder:** The recommended initial dose is 25 mg/day. Panic disorder, social anxiety disorder and premenstrual dysphoric disorder: 12.5 mg/day**. CONTRAINDICATIONS**: The use of MAOIs intended to treat a psychiatric disorder with Paroxetine or within 14 days of stopping treatment with Paroxetine is contraindicated because of an increased risk of serotonin syndrome. Concomitant use with thioridazine and pimozide is contraindicated. **PRECAUTIONS**: **General:** ***Activation of Mania/Hypomania,*** there have been reports of serious discontinuation symptoms. Patients should be monitored for these symptoms when discontinuing treatment with Paroxetine. Some studies have shown that the efficacy of tamoxifen, as measured by the risk of breast cancer relapse/mortality, may be reduced when co-prescribed with Paroxetine as a result of Paroxetine's irreversible inhibition of CYP2D6, akathisia, Hyponatremia, abnormal bleeding and bone fracture. **DRUG INTERACTIONS**: Drugs that interfere with hemostasis (e.g., NSAIDS, aspirin, and warfarin) , tryptophan , pimozide , serotonergic drugs , warfarin triptans, cimetidine , phenobarbital , phenytoin, drugs metabolized by CYP2D6 , tricyclic antidepressants , alcohol , lithium , digoxin , theophylline and fosamprenavir/ritonavir. **ADVERSE REACTIONS**: acute pancreatitis, elevated liver function tests (the most severe cases were deaths due to liver necrosis, and grossly elevated transaminases associated with severe liver dysfunction), Guillain-Barré syndrome, Stevens-Johnson syndrome, toxic epidermal necrolysis, priapism, syndrome of inappropriate ADH secretion, symptoms suggestive of prolactinemia and galactorrhoea, extrapyramidal symptoms which have included akathisia, bradykinesia, cogwheel rigidity, dystonia, hypertonia, oculogyric crisis which has been associated with concomitant use of pimozide; tremor and trismus; status epilepticus, acute renal failure, pulmonary hypertension, allergic alveolitis, anaphylaxis, eclampsia, laryngismus, optic neuritis, porphyria, restless legs syndrome (RLS), ventricular fibrillation, ventricular tachycardia (including torsade de pointes), thrombocytopenia, hemolytic anemia, events related to impaired hematopoiesis (including aplastic anemia, pancytopenia, bone marrow aplasia, and agranulocytosis), vasculitic syndromes (such as Henoch-Schönlein purpura), premature births in pregnant women, chills, face edema, fever, flu syndrome, malaise; rare were abscess, anaphylactoid reaction, anticholinergic syndrome, hypothermia angina pectoris, bradycardia, hematoma, hypertension, hypotension, palpitation, postural hypotension, supraventricular tachycardia, syncope, bruxism, dysphagia, eructation, gastritis, gastroenteritis, gastroesophageal reflux, gingivitis, hemorrhoids, arthritis, bursitis, and tendonitis; rare were myasthenia, myopathy, myositis, amnesia, convulsion, depersonalization, dystonia, emotional lability, hallucinations, hyperkinesias and hypesthesia.

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IN/ Paradise XR 12.5mg /Oct-2015/01/AbPI
(Additional information is available on request)