

CLONOTRIL-P

To be sold by retail on the prescription of a Psychiatrist only.

Abbreviated Prescribing information for CLONOTRIL-P (Paroxetine Controlled Release and Clonazepam Capsules) [Please refer the complete prescribing information available at www.torrentpharma.com] **PHARMACOLOGICAL PROPERTIES:** Paroxetine is a potent and selective inhibitor of 5-hydroxytryptamine (5-HT, serotonin) uptake and its antidepressant action and effectiveness in the treatment of OCD, Social Anxiety disorder/Social Phobia, General Anxiety Disorder, Post-Traumatic Stress Disorder and Panic Disorder is thought to be related to its specific inhibition of 5-HT uptake in brain neurones. Clonazepam exhibits pharmacological properties which are common to benzodiazepines and include anticonvulsive, sedative, muscle relaxing and anxiolytic effects. **INDICATIONS:** For the treatment of patients with co-morbid depression and anxiety **DOSAGE AND ADMINISTRATION:** The recommended dose is once daily in the morning with food. **CONTRAINDICATIONS:** Contraindicated in combination with monoamine oxidase inhibitors (MAOIs). It should not be used in combination with thioridazine, and with known sensitivity to benzodiazepines, acute pulmonary insufficiency, severe respiratory insufficiency, sleep apnoea syndrome, myasthenia gravis and severe hepatic insufficiency. **PRECAUTIONS:** It should not be used in the treatment of children and adolescents under the age of 18 years, depression associated with an increased risk of suicidal thoughts, self harm and suicide (suicide-related events) are reported. Also akathisia, neuroleptic malignant syndrome-like events may occur. Caution is recommended in patients with severe renal impairment or in those with hepatic impairment, patients with epilepsy, diabetes, renal impairment, seizures, electroconvulsive therapy and glaucoma, cardiac conditions, hyponatraemia, haemorrhage, prolonged use of benzodiazepines may result in dependence with withdrawal symptoms on cessation of use. **DRUG INTERACTIONS:** Serotonergic drugs, pimozide, neuromuscular blockers, fosamprenavir/ritonavir, procyclidine, anticonvulsants, oral anticoagulants, NSAIDs/acetylsalicylic acid, pravastatin, cimetidine, disulfiram, fluvoxamine, beta-blockers, calcium channel blockers, clonidine, diazoxide, diuretics, hydralazine, methyldopa, minoxidil, nitrates or nitroprusside. and ritonavir, Drugs that inhibit CYP2D6, calcium antagonists, anti-arrhythmic, clonidine, digitalis, insulin and oral anti-diabetic drugs, anaesthetics, digoxin, warfarin, acetaminophen, amlodipine, glibenclamide, simvastatin, hydrochlorothiazide and ibuprofen. **ADVERSE REACTIONS:** Thrombocytopenia, severe and potentially fatal allergic reactions, syndrome of inappropriate anti-diuretic hormone secretion increases in cholesterol levels, decreased appetite, increases in cholesterol levels, decreased appetite, somnolence, insomnia, agitation, abnormal dreams, confusion, hallucinations, manic reactions, anxiety, depersonalisation, panic attacks, akathisia, suicidal ideation, suicidal behaviour and aggression, dizziness, tremor, headache, concentration impaired, extrapyramidal disorders, convulsions, restless legs syndrome, serotonin syndrome, blurred vision, mydriasis, acute glaucoma, tinnitus, sinus tachycardia, bradycardia, transient increases or decreases in blood pressure, postural hypotension, yawning, nausea, constipation, diarrhoea, vomiting, dry mouth, gastrointestinal bleeding, elevation of hepatic enzymes, hepatitis, sweating, skin rashes, pruritis, severe cutaneous adverse reactions, urinary retention, urinary incontinence, sexual dysfunction, hyperprolactinaemia/galactorrhoea, menstrual disorders (including menorrhagia, metrorrhagia, amenorrhoea, menstruation delayed and menstruation irregular), priapism, loss of libido, impotence, arthralgia, myalgias, asthenia, body weight gain, peripheral oedema, withdrawal symptoms, urinary incontinence, blood dyscrasia and endocrine disorders.

MARKETED BY:



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(Additional information is available on request)