Summary of prescribing information for CLONIL tablets

Active Ingredient: Each tablet of CLONIL contains: Clomipramine hydrochloride 10mg, 25mg, 50mg. **Indication:** Obsessive compulsive disorders, phobic states and depression (when sedation is required). **Dosage:** adults: initiated 25 mg daily and gradually increased, as tolerated, to approximately 100 mg during the first 2 weeks. It should be given in divided doses with meals to reduce gastrointestinal side effects. Then, the dosage may be increased gradually over the next several weeks, up to a maximum of 250 mg daily. Children and Adolescents: starting dose is 25 mg daily and should be gradually increased (also given in divided doses with meals) during the first 2 weeks, as tolerated, daily maximum of 3 mg/kg or 100 mg, whichever is smaller. Dosage may be increased gradually over the next several weeks up to a daily maximum of 3 mg/kg or 200 mg, whichever is smaller. After titration, the total daily dose may be given once daily at bedtime to minimize daytime sedation. Maintenance dose of 50 to 100mg daily in 2/3 divided doses is indicated. **Contraindications:** Hypersensitivity to tricyclic compounds belonging to dibenzazepine group. Should not be administered simultaneously with MAO inhibitors (MAOIs). During the acute recovery period after a myocardial infarction. **Warning and precautions:** Cardiovascular effects: orthostatic postural hypotension may occur in many patients. Should not be used in presence of pronounced cardiac failure, recent myocardial infarction or ischemia heart disease. Cardiotoxicity may occur in hyperthyroid medication. Seizure: may precipitate epileptic seizures in predisposed patients. Epileptic patients should be monitored regularly. Obstructive jaundice, bone marrow depression, agranulocytosis have been reported. The possibility of suicide should be considered. Activation of schizophrenia or aggravation of psychosis may occur. Should be used with caution due to its anticholinergic effect, in patients receiving Electro-convulsive therapy and reduced gastrointestinal motility. **Pregnancy & Lactation:** Should not be administered during first trimester of pregnancy and during lacatation. The potential benefits should be weighed against possible hazards. **Interaction:** alcohol: can alter motor skills. Anticholinergic drugs: may produce additive effects with tricyclic antidepressants. This may result in serious effects such as glaucoma and urinary retention. MAOIs: resulting in CNS toxicity marked by hyperpyrexia, convulsions and coma. Thyroid Hormones: may potentiate the psychotropic effect of tricyclics. CNS depressants: Enhanced sedation and impaired physical coordination can occur. **Adverse reactions:** most common gastrointestinal complaints, including dry mouth, constipation, nausea, dyspepsia, and anorexia; nervous system complaints, including somnolence, tremor, dizziness, nervousness, and myoclonus; genitourinary complaints, including changed libido, ejaculatory failure, impotence, and micturition disorder; and other miscellaneous complaints, including fatigue, sweating, increased appetite, weight gain, and visual changes. **Overdose:** Symptoms: vary in severity depending upon factors such as the amount of drug absorbed, the age of the patient, and the time elapsed since drug ingestion. Critical manifestations include cardiac dysrhythmias, severe hypotension, convulsions, and CNS depression including coma. Changes in the electrocardiogram, particularly in QRS axis or width, are clinically significant indicators of tricyclic toxicity. Other CNS manifestations may include drowsiness, stupor, ataxia, restlessness, agitation, delirium, severe perspiration, hyperactive reflexes, muscle rigidity, and athetoid and choreiform movements. Cardiac abnormalities may include tachycardia, signs of congestive heart failure, and in very rare cases, cardiac arrest. Respiratory depression, cyanosis, shock, vomiting, hyperpyrexia, mydriasis, and oliguria or anuria may also be present. Management: Obtain an ECG and immediately initiate cardiac monitoring. Protect the patient's airway, establish an intravenous line, and initiate gastric decontamination (gastric lavage, followed by activated charcoal). Emesis is contraindicated. Use of hyperventilation and sodium bicarbonate should be done with extreme caution. Hemoperfusion may be beneficial in acute refractory cardiovascular instability in some patients with acute toxicity. Seizures should be controlled with benzodiazepines, or if these are ineffective, other anticonvulsants (e.g., phenobarbital, phenytoin). Physostigmine is not recommended except to treat life-threatening symptoms that have been unresponsive to other therapies.

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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