ARKAMIN 100

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

Abbreviated Prescribing information for ARKAMIN (Clonidine Hydrochloride Tablets**)**

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Clonidine stimulates alpha-adrenoreceptors in the brain stem. This action results in reduced sympathetic outflow from the central nervous system and in decreases in peripheral resistance, renal vascular resistance, heart rate, and blood pressure. Clonidine hydrochloride tablets act relatively rapidly. The patient's blood pressure declines within 30 to 60 minutes after an oral dose, the maximum decrease occurring within 2 to 4 hours. Renal blood flow and glomerular filtration rate remain essentially unchanged. Normal postural reflexes are intact; therefore, orthostatic symptoms are mild and infrequent.

INDICATION: It is indicated for, the treatment of hypertension.

DOSAGE AND ADMINISTRATION:

Adults: The dose of clonidine hydrochloride tablets must be adjusted according to the patient's individual blood pressure response. The following is a general guide to its administration.

Initial Dose: 0.1 mg tablet twice daily (morning and bedtime). Elderly patients may benefit from a lower initial dose.

Maintenance Dose: Further increments of 0.1 mg per day may be made at weekly intervals if necessary until the desired response is achieved. Taking the larger portion of the oral daily dose at bedtime may minimize transient adjustment effects of dry mouth and drowsiness. The therapeutic doses most commonly employed have ranged from 0.2 mg to 0.6 mg per day given in divided doses.

CONTRAINDICATION: Clonidine hydrochloride tablets should not be used in patients with known hypersensitivity to clonidine and other active ingredients.

WARNINGS & PRECAUTIONS: Withdrawal: Patients should not stop clonidine therapy suddenly as it may lead to symptoms like nervousness, agitation, headache, and tremors, abrupt cessation can cause a rapid rise in blood pressure and elevated catecholamine levels. This risk is higher with higher doses, concurrent beta-blocker use, or abrupt withdrawal in children due to vomiting risks. To avoid withdrawal symptoms, clonidine should be tapered gradually over 2 to 4 days. **Excessive Blood Pressure Rise** after clonidine discontinuation, it can be reversed with oral clonidine or intravenous phentolamine. If clonidine is used with a beta-blocker, the beta-blocker should be withdrawn several days before clonidine to prevent rebound hypertension. **Precautions**: Localized contact sensitization to transdermal clonidine may lead to generalized skin rash with oral clonidine substitution. Allergic reactions, including rash or swelling, may occur with both transdermal and oral forms. Clonidine's sympatholytic action may worsen sinus node dysfunction or AV block, especially with other sympatholytic drugs. Patients with these conditions may require intervention like IV atropine or isoproterenol. Clonidine may not be effective in hypertension due to pheochromocytoma. Clonidine should be administered until 4 hours before surgery and resumed promptly afterward. **Blood pressure must be closely monitored** during surgery with additional control measures available if needed.

DRUG INTERACTION:

Clonidine may potentiate the CNS-depressive effects of alcohol, barbiturates or other sedating drugs. If a patient receiving clonidine hydrochloride is also taking tricyclic antidepressants, the

hypotensive effect of clonidine may be reduced, necessitating an increase in the clonidine dose. If a patient receiving clonidine is also taking neuroleptics, orthostatic regulation disturbances (e.g., orthostatic hypotension, dizziness, fatigue) may be induced or exacerbated. Monitor heart rate in patients receiving clonidine concomitantly with agents known to affect sinus node function or AV nodal conduction, e.g., digitalis, calcium channel blockers, and beta-blockers. Sinus bradycardia resulting in hospitalization and pacemaker insertion has been reported in association with the use of clonidine concomitantly with diltiazem or verapamil. Amitriptyline in combination with clonidine enhances the manifestation of corneal lesions in rats. Based on observations in patients in a state of alcoholic delirium it has been suggested that high intravenous doses of clonidine may increase the arrhythmogenic potential (QTprolongation, ventricular fibrillation) of high intravenous doses of haloperidol. Causal relationship and relevance for clonidine oral tablets have not been established.

ADVERSE REACTIONS: Most adverse effects are mild and tend to diminish with continued therapy. The most frequent are dry mouth, drowsiness, dizziness, constipation and sedation, Fatigue, fever, headache, pallor, weakness, and withdrawal syndrome. ***Cardiovascular:*** Bradycardia, congestive heart failure, electrocardiographic abnormalities (i.e., sinus node arrest, junctional bradycardia, high degree AV block and arrhythmias), orthostatic symptoms, palpitations, Raynaud's phenomenon, syncope, and tachycardia. ***Central Nervous System:*** Agitation, anxiety, delirium, delusional perception, hallucinations (including visual and auditory), insomnia, mental depression, nervousness, other behavioral changes, paresthesia, restlessness, sleep disorder, and vivid dreams or nightmares. ***Dermatological:*** Alopecia, angioneurotic edema, hives, pruritus, rash, and urticaria. ***Gastrointestinal:*** Abdominal pain, anorexia, constipation, hepatitis, malaise, mild transient abnormalities in liver function tests, nausea, parotitis, pseudo-obstruction (including colonic pseudo-obstruction), salivary gland pain, and vomiting. ***Genitourinary:*** Decreased sexual activity, difficulty in micturition, erectile dysfunction, loss of libido, nocturia, and urinary retention. ***Hematologic:*** Thrombocytopenia. ***Metabolic:*** Gynecomastia, transient elevation of blood glucose or serum creatine phosphokinase, and weight gain. ***Musculoskeletal:*** Leg cramps and muscle or joint pain. ***Oro-otolaryngeal:*** Dryness of the nasal mucosa. ***Ophthalmological:*** Accommodation disorder, blurred vision, burning of the eyes, decreased lacrimation, and dryness of eyes.

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(Additional information is available on request)