ARKAMIN 150

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: The hypotensive effect of clonidine hydrochloride is produced mostly by its central effect or reducing sympathetic drive. In this respect clonidine hydrochloride differs from previously used anti-hypertensive. Clonidine hydrochloride neither depletes major catecholamine stores, nor acts as a ganglion blocking agent. The specific and different mode of action of clonidine hydrochloride leads to benefits such as reduced incidence of postural hypotension and only rarely an effect on libido.

INDICATION: It is indicated for, all grades of essential hypertension. And renal hypertension.

DOSAGE AND ADMINISTRATION: Tablets: 75 micrograms (half a tablet) two or three times a day. Increase the daily dosage by half-tablet (75 micrograms) increments until desired control of blood pressure is achieved. In those patients to whom ARKAMIN is given as sole therapy, there may be in the early months of treatment a need to gradually increase dosage to achieve optimal control. Dosage adjustment by small increments is desirable up to a maximum recommended dose of 900 micrograms per day. In the early stages of treatment, some associated fluid retention may be minimised by the concomitant use of a thiazide diuretic.

Maintenance: 150 micrograms (one tablet) to 300 micrograms (two tablets) three times a day. In impaired renal and hepatic function the half-life is prolonged and the dosage regimen should be monitored carefully.

CONTRAINDICATION: Clonidine hydrochloride tablets should not be used in patients with known hypersensitivity to active ingredient.

WARNINGS & PRECAUTIONS: Special care should be exercised in treating patients with these conditions as lowering blood pressure could potentially worsen mental status in cerebrovascular disease patients. Adjustments in ARKAMIN dosage may be necessary when used with tricyclic antidepressants. **ARKAMIN may cause a transient rise in blood sugar** due to its alpha-adrenomimetic effects, but it does not induce diabetes mellitus. **Patients with diabetes** should be monitored for increased anti-diabetic therapy needs. **ARKAMIN should be used cautiously** in patients with mild to moderate bradyarrhythmia, cerebral or peripheral perfusion disorders, polyneuropathy, and constipation. **ARKAMIN is not effective for hypertension** caused by Phaeochromocytoma**. Dosage adjustment** is necessary in patients with renal insufficiency due to extensive excretion of ARKAMIN and its metabolites in urine. **Heart failure or severe coronary heart disease:** Monitoring during treatment with ARKAMIN is crucial in patients with heart failure. **Discontinuation of ARKAMIN** should be gradual over more than 7 days to avoid rebound hypertension and other withdrawal symptoms like restlessness, palpitations, and headache. **Sudden cessation**, especially after high-dose or prolonged treatment, may lead to severe rebound hypertension, which can be managed with intravenous phentolamine. When **discontinuing long-term treatment** with β-blockers and ARKAMIN concurrently, the β-blocker should be phased out gradually first. Patients wearing contact lenses should be aware that ARKAMIN may reduce lacrimation. **Abrupt withdrawal of ARKAMIN** before anesthesia is not recommended; maintenance therapy may be preferable, and if cessation is necessary, it should be gradual and monitored. There is limited data on ARKAMIN use in the elderly Patients and insufficient evidence to recommend its use in children and adolescents.

DRUG INTERACTION: Antihypertensive therapy: care should be taken as even a small dose of clonidine may further lower blood pressure and necessitate adjustment of the antihypertensive regime. Avoid Additional Clonidine: additional clonidine should not be prescribed for conditions like migraine prophylaxis or menopausal flushing. Clonidine (ARKAMIN) can enhance the effects of alcohol, sedatives, hypnotics, or other centrally acting substances. Clonidine hasn't been associated with eye damage, regular follow-up exams like ophthalmoscopy are recommended. Interference by NSAIDs: can reduce the effectiveness of clonidine by raising blood pressure or inducing fluid retention. Drugs like phentolamine (Alpha-2 Adrenergic Blockers) that block alpha-2 adrenergic receptors may counteract clonidine's effects, depending on dosage. Drugs such as beta-blockers and digitalis glycosides can cause or worsen bradycardia (slow heart rhythm) when taken with clonidine. Concomitant use of beta-blockers with clonidine may potentially cause or worsen peripheral vascular disorders. Interaction with Tricyclic Antidepressants and Neuroleptics: can reduce clonidine's antihypertensive effects and disturb orthostatic regulation. Intravenous doses of clonidine combined with high doses of haloperidol may increase the risk of arrhythmias (QT-prolongation, ventricular fibrillation), especially noted in patients with delirium tremens.

ADVERSE REACTIONS: Gynaecomastia, Depression, sleep disorder, Delusional perception, hallucination, nightmare Confusional state, libido decreased, Dizziness, sedation, Headache, Paraesthesia, Lacrimation decreased, Accommodation disorder, Sinus bradycardia, Atrioventricular block, Bradyarrhythmia, Orthostatic hypotension, Raynaud's phenomenon, Nasal dryness, Dry mouth, Constipation, nausea, salivary gland pain, vomiting, Colonic pseudo- obstruction, Erectile dysfunction, Pruritus, rash, urticarial, Alopecia, Fatigue, Malaise, Blood glucose increased.

MANUFACTURED BY:

TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA

IN/ARKAMIN 150 mcg/JUN-2024/02/ABPI
(Additional information is available on request)