

ARKAMIN H

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

Abbreviated Prescribing information for ARKAMIN H (Clonidine Hydrochloride and Hydrochlorothiazide Tablets) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Clonidine Hydrochloride

Clonidine hydrochloride has been shown to have both central and peripheral sites of action. With long-term treatment Clonidine hydrochloride reduces the responsiveness of peripheral vessels to vasoconstrictor and vasodilator substances and to sympathetic nerve stimulation. Early in treatment, however, blood pressure reduction is associated with a central reduction of sympathetic outflow and increased vagal tone.

Hydrochlorothiazide

Hydrochlorothiazide blocks the reabsorption of sodium and chloride ions, and it thereby increases the quantity of sodium traversing the distal tubule and the volume of water excreted. A portion of the additional sodium presented to the distal tubule is exchanged there for potassium and hydrogen ions. With continued use of hydrochlorothiazide and depletion of sodium, compensatory mechanisms tend to increase this exchange and may produce excessive loss of potassium, hydrogen and chloride ions. **INDICATIONS:** For the treatment of hypertension

DOSAGE AND ADMINISTRATION: Dosage: As directed by the Physician.

CONTRAINDICATION: Clonidine hydrochloride should not be used in patients with known hypersensitivity to the active ingredient or other components of the product, and in patients with severe Bradyarrhythmia resulting from either sick sinus syndrome or AV block of 2nd or 3rd degree. In case of rare hereditary conditions that may be incompatible with an excipient of the product (please refer to section 4.4 Special Warnings and Precautions for Use) the use of the product is contraindicated.

- Hypersensitivity to this product or to other sulfonamide-derived drugs.
- Anuria.

WARNINGS & PRECAUTION:

Caution should be exercised in patients with Raynaud's disease or other peripheral vascular disease. As with all drugs used in hypertension Clonidine hydrochloride should be used with caution in patients with cerebrovascular or coronary insufficiency.

Clonidine hydrochloride should also be used with caution in patients with mild to moderate Bradyarrhythmia such as low sinus rhythm, and with polyneuropathy or constipation.

Patients with a known history of depression should be carefully supervised while under long-term treatment with Clonidine hydrochloride as there have been occasional reports of further depressive episodes during oral treatment in such patients. Use with caution in severe renal

disease. In patients with renal disease, thiazides may precipitate azotemia. Cumulative effects of the drug may develop in patients with impaired renal function. General: All patients receiving diuretic therapy should be observed for evidence of fluid or electrolyte imbalance: namely, hyponatremia, hypochloremic alkalosis, and hypokalemia. Serum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Warning signs or symptoms of fluid and electrolyte imbalance, irrespective of cause, include dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, confusion, seizures, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, and gastrointestinal disturbances such as nausea and vomiting. Hypokalemia may develop, especially with brisk diuresis, when severe cirrhosis is present or after prolonged therapy. Interference with adequate oral electrolyte intake will also contribute to hypokalemia.

DRUG INTERACTIONS: The reduction in blood pressure induced by clonidine can be further potentiated by concurrent administration of other hypotensive agents. This can be of therapeutic use in the case of other antihypertensive agents such as diuretics, vasodilators, beta-receptor blockers, calcium antagonists and ACE-inhibitors, but the effect of alpha1-blockers is unpredictable. Drug Interactions: When given concurrently the following drugs may interact with thiazide diuretics. Alcohol, Barbiturates, or Narcotics: Potentiation of orthostatic hypotension may occur. Antidiabetic Drugs (Oral Agents and Insulin): Dosage adjustment of the antidiabetic drug may be required. Other Antihypertensive Drugs: Additive effect or potentiation. Cholestyramine and Colestipol Resins: Absorption of hydrochlorothiazide is impaired in the presence of anionic exchange resins. Single doses of either cholestyramine or colestipol resins bind the hydrochlorothiazide and reduce its absorption from the gastrointestinal tract by up to 85% and 43%, respectively.

ADVERSE REACTIONS: • Dizziness, feeling tired and more relaxed than usual (sedation) • Feeling dizzy when you stand up (because your blood pressure has fallen sharply) • Dry mouth • Depression, sleeping problems • Headache • Constipation, feeling sick (nausea), pain below the ear (from the salivary gland), being sick (vomiting) • Erectile dysfunction • Fatigue • Problems with understanding what is happening around you, hallucinations, nightmares • Your hands and feet feeling different ('altered sensation') • Regular unusually slow heart beat • Raynaud's phenomenon (a problem with circulation to the fingers and toes) • Itching, rash, urticaria (nettle rash) • A feeling of discomfort and fatigue ('malaise') • Breast growth ('gynaecomastia') in men • Dry eyes • Irregular heartbeat • Drying out of the lining of the nose • Pseudo-obstruction of the large bowel, which causes colicky pain, vomiting and constipation. Contact your doctor straight away if you have all these side effects. • Hair loss • Increase in your blood sugar • Confusion, loss of libido • Blurred vision • Abnormally slow heart beat Two cases of hepatitis (inflammation of the liver) have also been reported. This might show up in some blood tests. Your body may hold onto more water than usual (fluid retention). More serious (contact your doctor as soon as possible if any of the following occur): • exhaustion or muscle weakness • very frequent urination or constipation • unexplained fever or sore throat • abnormal bleeding or bruising • persistent infection • fast heart beat • jaundice – yellowing of the skin and eyes • dehydration Allergic reaction (Stop medicine and see doctor immediately):

MARKETED BY:



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IN/ ARKAMIN H 100 mcg, 20 mg /Jul-2019/01/AbPI

(Additional information is available on request)