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Clonidine Hydrochloride and Chlorthalidone (Clorpres)

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CLORPRES (clonidine hydrochloride and chlorthalidone) ® is generally well tolerated. Most adverse effects are mild and tend to diminish with continued therapy. The most frequent (which appear to be dose-related) are dry mouth, occurring in about 40 of 100 patients; drowsiness, about 33 in 100; dizziness, about 16 in 100; constipation and sedation, each about 10 in 100. In addition to the reactions listed above, certain less frequent adverse experiences, which are shown below, have also been reported

in patients receiving the component drugs of CLORPRES (clonidine hydrochloride and chlorthalidone) ® but in many cases patients were receiving concomitant medication and a causal relationship has not been established:

Clonidine Hydrochloride

Nausea and vomiting, about 5 in 100 patients; anorexia and malaise, each about 1 in 100; mild transient abnormalities in liver function tests, about ***Gastrointestinal:*** 1 in 100; rare reports of hepatitis; parotitis, rarely.

Weight gain, about 1 in 100 patients; gynecomastia, about 1 in 1000, transient elevation of blood glucose or serum creatine phosphokinase, rarely. ***Metabolic:***

Nervousness and agitation, about 3 in 100 patients; mental depression, about 1 in 100; headache, about 1 in 100; insomnia, about 5 in ***Central Nervous System:*** 1000. Vivid dreams or nightmares, other behavioral changes, restlessness, anxiety, visual and auditory hallucinations and delirium have been reported.

Orthostatic symptoms, about 3 in 100 patients; palpitations and tachycardia, and bradycardia, each about 5 in 1000. Raynaud's phenomenon, ***Cardiovascular:*** congestive heart failure, and electrocardiographic abnormalities, i.e., conduction disturbances and arrhythmias, have been reported rarely. Rare cases of sinus bradycardia and atrioventricular block have been reported, both with and without the use of concomitant digitalis.

Rash, about 1 in 100 patients; pruritus, about 7 in 1000; hives, angioneurotic edema and urticaria, about 5 in 1000, alopecia, about 2 in 1000.***Dermatological:***

Decreased sexual activity, impotence and loss of libido, about 3 in 100 patients; nocturia, about 1 in 100; difficulty in micturition, about 2 in 1000; ***Genitourinary:*** urinary retention, about 1 in 1000.

Weakness, about 10 in 100 patients; fatigue, about 4 in 100; discontinuation syndrome, about 1 in 100; muscle or joint pain, about 6 in 1000 and cramps of ***Other:*** the lower limbs, about 3 in 1000. Dryness, burning of the eyes, blurred vision, dryness of the nasal mucosa, pallor, weakly positive Coombs' test, increased sensitivity to alcohol and fever have been reported.

Chlorthalidone

Anorexia, gastric irritation, nausea, vomiting, cramping, diarrhea, constipation, jaundice (intrahepatic cholestatic jaundice), pancreatitis. ***Gastrointestinal:***

Dizziness, vertigo, paresthesias, headache, xanthopsia. ***Central Nervous System:***

Leukopenia, agranulocytosis, thrombocytopenia, aplastic anemia. ***Hematologic:***

Purpura, photosensitivity, rash, urticaria, necrotizing angiitis (vasculitis) (cutaneous vasculitis), Lyell's syndrome (toxic epidermal ***Dermatologic-Hypersensitivity:*** necrolysis).

Orthostatic hypotension may occur and may be aggravated by alcohol, barbiturates or narcotics. ***Cardiovascular:***

Hyperglycemia, glycosuria, hyperuricemia, muscle spasm, weakness, restlessness, impotence. ***Other Adverse Reactions:***

Whenever adverse reactions are moderate or severe, chlorthalidone dosage should be reduced or therapy withdrawn.