Olmesartan HCT BSS [1]

Olmesartan medoxomil HCT Sandoz

20 mg / 12.5 mg coated tablets. Each coated tablet contains 20 mg olmesartan medoxomil and 12.5 mg hydrochlorothiazide. **Olmesartan medoxomil HCT Sandoz** 40 mg / 12.5 mg coated tablets. Each coated tablet contains 40 mg of olmesartan medoxomil and 12.5 mg of hydrochlorothiazide. **Indications:** Treatment of essential hypertension. The fixed-dose combination of **Olmesartan medoxomil Sandoz** is indicated in adult patients whose blood pressure is not adequately controlled with **Olmesartan medoxomil HCT Sandoz** monotherapy. **Dosage: Olmesartan medoxomil HCT Sandoz** is administered once a day. In patients whose blood pressure is not adequately controlled by the optimal 20 mg dose of **Olmesartan medoxomil** monotherapy, **Olmesartan medoxomil HCT Sandoz** 20 mg / 12.5 mg may be administered. The fixed-dose combination of Olmesartan medoxomil / Hydrochlorothiazide 40 mg / 12.5 mg is indicated in adult patients whose blood pressure is not adequately controlled with olmesartan medoxomil 40 mg monotherapy. The same dose of the combination is recommended in elderly patients (? 65 years) as in adults. **Renal impairment:** When Olmesartan medoxomil / Hydrochlorothiazide is used in patients with mild to moderate renal impairment (creatinine clearance 30-60 ml / min), periodic monitoring of renal function is advised. The maximum dose in patients with mild to moderate renal impairment is 20 mg once daily, given the limited experience with higher doses in this group of patients. **Hepatic impairment:** should be used with caution in patients with mild to moderate hepatic impairment. **Contraindications:** Hypersensitivity to the active substance, to any of the excipients or to other drugs derived from sulfonamide. Severe renal failure (the 40 mg / 12.5 mg dose is contraindicated in all stages of renal failure). Refractory hypokalemia, hypercalcemia, hyponatremia, and symptomatic hyperuricemia. Moderate and severe liver failure, cholestasis, and biliary obstructive disorders. Second and third trimester of pregnancy. Concomitant use with aliskiren is contraindicated in patients with diabetes mellitus or renal failure. Precautions for use: An increased risk of nonmelanoma skin cancer (NSCLC) [basal cell carcinoma (CBC) and squamous cell carcinoma (CEC)] has been observed with exposure to increasing cumulative doses of hydrochlorothiazide (HCTZ) in two epidemiological studies, based on the Danish National Cancer Registry. The photosensitizing effects of HCTZ could act as a possible mechanism of NSCLC. Symptomatic hypotension may occur, especially after the first dose, in patients with volume and / or sodium depletion, due to intense diuretic treatment, dietary salt restriction, diarrhea, or vomiting. These disorders must be corrected before **Olmesartan medoxomil HCT Sandoz** is administered. In patients in whom vascular tone and renal function depend predominantly on the activity of the system renin angiotensin aldosterone, treatment with drugs that affect this system has been associated with acute hypotension, azotemia, oliguria or, rarely, acute renal failure. . There is an increased risk of severe hypotension and renal failure when patients with bilateral renal artery stenosis or renal artery stenosis in the case of a single functional kidney are treated with medicinal products that affect the renin angiotensin aldosterone system. In patients with mild to moderate renal impairment (creatinine clearance 30 ml / min - 60 ml / min) Olmesartan medoxomil / Hydrochlorothiazide 20 mg / 12.5 mg should be administered with caution and periodic monitoring of serum levels of potassium, creatinine and uric acid. Azotemia associated with thiazide diuretics may occur in patients with renal failure. If progressive renal failure is evident, treatment should be carefully reevaluated, considering discontinuation of diuretic therapy. There is evidence that concomitant use of angiotensin converting enzyme (ACE) inhibitors, angiotensin II receptor antagonists (ARA II), or aliskiren increases the risk of hypotension, hyperkalemia, and decreased kidney function (including acute renal failure). Consequently, dual blocking of SARS through the combined use of ACE inhibitors, ARA II or aliskiren is not recommended. There is currently no experience with olmesartan medoxomil in patients with severe hepatic impairment. Minor disturbances in fluid and electrolyte balance during thiazide therapy may precipitate liver coma in patients with liver failure or progressive liver disease. Caution should be exercised in patients with mild to moderate hepatic impairment. As with other vasodilators, special caution is recommended in patients with aortic or mitral stenosis, or obstructive hypertrophic cardiomyopathy. It is not recommended in patients with primary aldosteronism. Treatment

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