

Olmesartan BSS ^[1]

Olmesartan Medoxomil Sandoz. Each coated tablet contains 10mg / 20mg / 40mg Olmesartan Medoxomil. **Excipient with known effect:** lactose. **Indications.** Treatment of essential hypertension. Treatment of hypertension in children and adolescents from 6 to <18 years of age. **Posology.** Adults. Recommended starting dose of 10 mg once a day. In patients whose blood pressure is not adequately controlled by this dose, it can be increased to 20 mg once daily as the optimal dose. If further reduction in blood pressure is required, it can be increased to a maximum of 40 mg daily or hydrochlorothiazide therapy added. No dosage adjustment is required in elderly patients. The maximum dose in patients with mild to moderate renal impairment is 20 mg once a day. In patients with moderate hepatic impairment, a starting dose of 10 mg daily is recommended and the maximum dose should not exceed 20 mg once daily. There is no experience in patients with severe hepatic impairment. Children and adolescents from 6 to <18 years of age: The recommended starting dose of **Olmesartan Medoxomil Sandoz** in children from 6 to <18 years of age is 10 mg once a day. In children whose blood pressure is not adequately controlled with this dose, the dose can be increased to 20 mg daily. If a further reduction in blood pressure is required, in children whose weight is \geq 35 kg, the dose can be increased to a maximum of 40 mg. In children whose weight is <35 kg, the daily dose should not exceed 20 mg. The safety and efficacy of **Olmesartan Medoxomil Sandoz** in children aged 1 to 5 years have not yet been established. **Olmesartan Medoxomil Sandoz** should not be used in children under 1 year of age for safety reasons and the absence of data in this age group. **Contraindications.** Hypersensitivity to the active substance or to any of the excipients. Pregnancy. Biliary obstruction. Concomitant use of angiotensin receptor antagonists (ARA II) - including olmesartan - or angiotensin converting enzyme (ACE) inhibitors with aliskiren in patients with Type 2 diabetes. **Precautions.** Symptomatic hypotension may occur in patients with volume and / or sodium depletion. Patients whose vascular tone and renal function depend mainly on the activity of the renin-angiotensin-aldosterone system. There is an increased risk of severe hypotension and renal insufficiency when patients with bilateral renal artery stenosis or single functional kidney artery stenosis are treated with drugs that affect the renin-angiotensin aldosterone system. It can cause hyperkalemia. Combination with lithium is not recommended. Special caution in patients with aortic or mitral valve stenosis, or with obstructive hypertrophic cardiomyopathy. Chronic severe diarrhea has been reported. If a patient develops these symptoms during **Olmesartan Medoxomil Sandoz** treatment and in the absence of other apparent etiologies, Olmesartan Medoxomil Sandoz® treatment should be discontinued immediately and should not be restarted. If diarrhea does not improve after a week of discontinuation, further specialist advice should be considered. Excessive drop in blood pressure in patients with ischemic heart disease or ischemic cerebrovascular disease can lead to myocardial infarction or stroke. A risk to the fetus during pregnancy cannot be excluded. It is not recommended during lactation. **Adverse effects.** Headache, flu-like symptoms, dizziness. Hypertriglyceridemia, hyperuricemia. Dizziness, headache Bronchitis, pharyngitis, cough, rhinitis. Gastroenteritis, diarrhea, abdominal pain, nausea, dyspepsia. Arthritis, back pain, skeletal pain. Hematuria, urinary tract infection. Pain, chest pain, peripheral edema, flu-like symptoms, fatigue. Increased liver enzymes, increased blood urea, increased creatinine phosphokinase in blood. **CDS V05 May 2017.**

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