Irbesartan BSS [1]

Irbesartan Sandoz. Tablets with film / coated tablets. Each tablet contains 150 mg or 300 mg of Irbesartan. Excipients with known effect: lactose monohydrate. Indications: Treatment of essential hypertension in adults. Treatment of kidney diseases in adult patients with hypertension and type 2 diabetes mellitus, as part of a regimen of antihypertensive medications. **Dosage:** The usual recommended start and maintenance dose is 150 mg once a day, it can be increased to 300 mg per day. In hypertensive patients with type 2 diabetes, therapy should be started with a dose of 150 mg of **Irbesartan Sandoz** per day, and should be adjusted to 300 mg once a day as the preferred maintenance dose for the treatment of kidney diseases. No dose adjustment is necessary in patients with impaired renal function. No dose adjustment is necessary in patients with mild to moderate hepatic impairment. There is no clinical experience with patients with severe hepatic insufficiency. Although a dose adjustment is usually not necessary for patients older than 75 years, initiation of therapy with 75 mg may be considered. The safety and efficacy of Irbesartan in children 0 to 18 years has not been established. **Contraindications:** Hypersensitivity to the active substances or any of the excipients. Pregnancy. Concomitant use of angiotensin receptor blockers (ARA) - including **Irbesartan Sandoz** - or angiotensin-converting enzyme (ACE) inhibitors with aliskiren in patients with type 2 diabetes. Precautions for use: Symptomatic hypotension may occur especially after the first dose, in patients with reduced volume and / or sodium by vigorous diuretic therapy, dietary salt restriction, diarrhea or vomiting. There is an increased risk of severe hypertension and renal failure when patients with bilateral renal artery stenosis or renal artery stenosis of a single kidney are treated with drugs that affect the renin-angiotensin-aldosterone system. Periodic monitoring of potassium and serum creatinine levels in patients with renal insufficiency is recommended. Hyperkalemia may occur during treatment with **Irbesartan Sandoz** especially in the presence of renal failure, open proteinuria due to diabetic kidney disease, and / or heart failure. It is recommended to closely monitor serum potassium in patients at risk. The combination of lithium with **Irbesartan Sandoz** is not recommended. Caution in patients suffering from mitral or aortic stenosis, or obstructive hypertrophic cardiomyopathy. The use of **Irbesartan Sandoz** in patients with primary hyperaldosteronism is not recommended. Excessive decrease in blood pressure in patients with ischemic heart disease or ischemic cardiovascular disease can lead to a myocardial infarction or stroke. Special precautions for excipients: This medicine contains lactose and sodium. **Common Adverse Events:** Orthostatic dizziness, orthostatic hypotension, dizziness, nausea, vomiting, musculoskeletal pain, fatigue, hypercalcemia, increases in plasma creatine kinase levels. Hypersensitivity reactions such as angioedema, rash, urticaria, anaphylactic reaction and anaphylactic shock may occur, although its frequency is unknown. **CDS V05 Feb 2019**

Links
[1] https://www.cac.sandoz.com/en/irbesartan-bss