# Safebul BSS [1]

**Safebul® 8 mg tablets.** Each tablet contains 8 mg of candesartan cilexetil. **Safebul® 16 mg tablets.** Each tablet contains 16 mg of candesartan cilexetil and **Safebul® 32 mg tablets.** Each tablet contains 32 mg of candesartan cilexetil. Excipients with known effect: lactose monohydrate. **Therapeutic indications**. Essential hypertension in adult patients. Hypertension treatment in children and adolescents between 6 and ?18 years of age. Adult patients with heart failure and impaired left ventricular systolic function (left ventricular ejection fraction ? 40%), when angiotensin-converting enzyme inhibitors (ACE inhibitors) are not tolerated or as combination therapy with an ACE inhibitor in patients with symptomatic heart failure, despite optimal therapy, or when mineralocorticoid receptor antagonists are not tolerated. **Posology.** Hypertension: the recommended starting dose and the usual maintenance dose is 8 mg once daily. The dose may be increased up to 16 mg once daily. If your blood pressure is not sufficiently controlled after 4 weeks of treatment with 16 mg once daily and up to a maximum of 32 mg once daily. Treatment should be adjusted according to the blood pressure response. **Safebul®** can also be administered with other antihypertensive agents. The addition of hydrochlorothiazide has shown an additive antihypertensive effect with various **Safebul®** dosages. **Use in older adults:** no need to adjust the starting dose in these patients. **Use in patients with intravascular volume reduction:** an initial dose of 4 mg can be considered in patients at risk of hypotension, such as patients with possible volume depletion. **Use in patients with renal impairment:** the starting dose is 4 mg in patients with renal impairment, including patients on haemodialysis. The dose should be adjusted according to the response. There is limited experience in patients with very severe or end-stage renal impairment ($Cl_{creatinine} \leq$ 15 ml / min). **Use in hepatic impairment:** an initial dose of 4 mg is recommended once daily in patients with mild to moderate hepatic impairment. The dose may be adjusted according to the response. **Safebul®** is contraindicated in patients with severe hepatic impairment and/or cholestasis. **Use in black patients: t**he antihypertensive effect of **Safebul®** is less pronounced in black patients than in patients of other races, as a result, dose adjustment of **Safebul®** and the use of a concomitant therapy may be more frequently necessary to control blood pressure in black patients than in patients of other races. **Use in the pediatric population:** children and adolescents between 6 and <18 years of age, the recommended starting dose is 4 mg once daily. For patients weighing <50 kg in whom blood pressure is not adequately controlled, the dose can be increased to a maximum of 8 mg once daily. For patients weighing ≥50 kg, in whom blood pressure is not adequately controlled, the dose can be increased to 8 mg once daily and then if it is required up to 16 mg once daily. Doses over 32 mg have not been studied in pediatric patients. **Safebul®** has not been studied in children with glomerular filtration rate less than 30 mL/min/1.73m$^2$. **Black pediatric patients:** the antihypertensive effect of **Safebul®** is less pronounced in black patients than in non-black patients. **Children between 1 and < 6 years of age:** safety and efficacy have not been established in children between 1 and 6 years of age. **Safebul®** is contraindicated in children younger than 1 year. **Dosage in heart failure:** the usual recommended starting dose of **Safebul®** is 4 mg once daily. Adjustment up to the desired dose of 32 mg once daily (maximum dose) or up to the maximum tolerated dose is done by doubling the dose at intervals of at least 2 weeks. **Safebul®** may be given with other treatment for heart failure, including ACE inhibitors, beta blockers, diuretics and digitalis or a combination of these drugs. **Safebul®** can be administered in conjunction with an ACE inhibitor in patients with symptomatic heart failure despite optimal standard therapy for heart failure when a mineralocorticoid receptor antagonist is not tolerated. **Contraindications:** hypersensitivity to **Safebul®** active substance or to any of the excipients. Pregnancy. Severe hepatic impairment and/or cholestasis. Concomitant use of angiotensin II receptor antagonists (ARAIIs), including **Safebul®** or an ACE inhibitor with aliskiren in patients with type 2 diabetes. Children under 1 year of age. **Precautions for use:** renal impairment. As with other renin inhibitors - angiotensin – aldosterone (RAAS), changes in renal function can be expected in sensitive patients treated with **Safebul®.** Use in pediatric patients, including patients with renal impairment: **Safebul®** has not been studied in children with a glomerular filtration rate of less than 30 mL/min/1.73m$^2$. For children with possible intravascular volume

**Source URL:**https://www.cac.sandoz.com/en/safebul-bss-0

**Links**
[1] https://www.cac.sandoz.com/en/safebul-bss-0