

Entresto[®] Sprinkle (sacubitril/valsartan) – New formulation approval

- On April 12, 2024, the [FDA approved](#) Novartis' [Entresto Sprinkle \(sacubitril/valsartan\)](#), a new oral pellets within capsule formulation of Entresto.
 - Entresto was previously available as an oral tablet.
- Entresto is approved to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure and for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older.
- Entresto Sprinkle carries a boxed warning for fetal toxicity.
- Entresto Sprinkle is contraindicated:
 - In patients with hypersensitivity to any component
 - In patients with a history of angioedema related to previous angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) therapy
 - With concomitant use of ACE inhibitors
 - With concomitant use of aliskiren in patients with diabetes.
- Warnings and precautions for Entresto Sprinkle include angioedema, hypotension, impaired renal function, and hyperkalemia.
- Refer to the Entresto Sprinkle drug label for complete dosing and administration recommendations.
- Novartis' launch plans for Entresto Sprinkle are pending. Entresto Sprinkle will be available as a 6 mg/6 mg and 15 mg/16 mg film-coated oral pellets within capsules.