

Aspruzyo Sprinkle™ (ranolazine) – New drug approval

- On February 28, 2022, the [FDA approved](#) Sun Pharma's [Aspruzyo Sprinkle \(ranolazine\)](#), for the treatment of chronic angina.
 - Aspruzyo Sprinkle may be used with beta-blockers, nitrates, calcium channel blockers, anti-platelet therapy, lipid-lowering therapy, angiotensin-converting enzyme inhibitors, and angiotensin receptor blockers.
- Aspruzyo Sprinkle is an extended-release granule formulation of ranolazine. Ranolazine is currently available generically as an extended-release [tablet](#). The tablet formulation shares the same indication as Aspruzyo Sprinkle.
- Aspruzyo Sprinkle is contraindicated in patients:
 - Taking strong inhibitors of CYP3A
 - Taking inducers of CYP3A
 - With liver cirrhosis.
- Warnings and precautions for Aspruzyo Sprinkle include QT interval prolongation and renal failure.
- The most common adverse reactions (> 4% and more common than with placebo) with Aspruzyo Sprinkle use were dizziness, headache, constipation, and nausea.
- The recommended initial dose of Aspruzyo Sprinkle is 500 mg orally twice daily and increased to 1000 mg orally twice daily, as needed, based on clinical symptoms.
 - The maximum recommended daily dose of Aspruzyo Sprinkle is 1000 mg twice daily.
 - Aspruzyo Sprinkle can be administered with soft food (eg, apple sauce and yogurt) or via nasogastric and gastric tube.
- Sun Pharma's launch plans for Aspruzyo Sprinkle are pending. Aspruzyo Sprinkle will be available as a 500 and 1000 mg extended-release granules.