

Landmarks Pharmacy News

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A New RX Symdeko (Trzacafto/ivacftor) Gets FDA Approval
It is a Cystic Fibrosis Combo Treatment



Treatment with Symdeko also resulted in a favorable safety profile; infective pulmonary exacerbation and cough were the most common adverse events seen across both treatment arms. Preliminary data from the ongoing EXTEND rollover study showed that lung function improvements and the safety and tolerability profiles seen in EVOLVE and EXPAND were sustained for up to 48 weeks of treatment.

Principal investigator of the EXTEND study, Patrick Flume, MD, added, "In particular, Symdeko is an important treatment option for patients who either never started or discontinued [Orkambi](#), and it also provides increased benefit over [Kalydeco](#) alone for patients with residual function mutations."

Symdeko will be available starting this week. It is co-packaged as tezacaftor 100mg/ ivacaftor 150mg fixed dose combination tablets and ivacaftor 150mg strength tablets in 56-count cartons (4-week supply).

The US Food and Drug Administration (FDA) has approved a new drug to treat [cystic fibrosis](#) (CF).

This new drug is called [Symdeko](#) (tezacaftor/ivacaftor). The FDA approved it for those with CF who are at least 12 years old and who have two copies of the *F508del* mutation. It is also approved for those who have at least one mutation in the CF gene that can be treated with Symdeko.

Patients with CF often experience lung infections and a decreased ability to breathe over time. In those with CF, a defective gene causes a thick, sticky buildup of mucus in the lungs and other organs.

People with CF inherit two abnormal CF genes (one from each parent) when they are born. Abnormal CF genes can result in various mutations. The most common CF mutation is called *F508del*.

“Symdeko is an important addition to the growing CF treatment arsenal and a much-needed option for individuals with the most common CF mutation,” said Dr. Michael Boyle, senior vice president for therapeutics development at the Cystic Fibrosis Foundation, in a press release.

Symdeko helps improve the function of a certain protein. As a result, the medication may reduce the chance of mucus in the lungs. Common side effects of Symdeko include headache, nausea, dizziness and stuffy nose. This medication may also cause liver damage. Avoid foods or drinks that contain grapefruit or Seville oranges while taking this medication.

The FDA granted approval of Symdeko to Vertex Pharmaceuticals.