



## Trikafta® (elixacaftor/tezacaftor/ivacaftor; ivacaftor) – Expanded indication, new strength

- On June 9, 2021, [Vertex announced the FDA approval of Trikafta \(elixacaftor/tezacaftor/ivacaftor; ivacaftor\)](#), for the treatment of cystic fibrosis (CF) in patients aged 6 years and older who have at least one *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene or a mutation in the *CFTR* gene that is responsive based on *in vitro* data.
  - Trikafta was previously approved for this indication in patients 12 years and older.
  - If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one *F508del* mutation or a mutation that is responsive based on *in vitro* data.
- In connection with the expanded indication, the FDA also approved a new strength of Trikafta (fixed-dose combination containing elixacaftor 50 mg, tezacaftor 25 mg and ivacaftor 37.5 mg co-packaged with ivacaftor 75 mg).
- The effectiveness of Trikafta in patients aged 6 to less than 12 years was extrapolated from patients aged 12 years and older with support from population pharmacokinetic analyses showing elixacaftor, tezacaftor and ivacaftor exposure levels in patients aged 6 to less than 12 years within the range of exposures observed in patients aged 12 years and older.
- In patients 6 to less than 12 years weighing less than 30 kg, the recommended oral morning dose is two tablets, each containing elixacaftor 50 mg/tezacaftor 25 mg/ivacaftor 37.5 mg. The recommended evening dose is one tablet of ivacaftor 75 mg.
- In patients 6 to less than 12 years weighing 30 kg or more and in patients 12 years and older, the recommended oral morning dose is two tablets, each containing elixacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg. The recommended evening dose is one tablet of ivacaftor 150 mg.



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