

## Name(s)

- **Generic:** elexacaftor/ivacaftor/tezacaftor (*e LEX a KAF tor / EYE va KAF tor / TEXZ a KAF tor*)
- **Brand:** Trikafta (currently brand only)

## Therapeutic Category

- Cystic Fibrosis Transmembrane Conductase Regulator (**CFTR**) Combination Product

## Indication(s)

1. Treatment of **Cystic Fibrosis**
  - Only in patients that have at least one F508del mutation in the CFTR gene
  - Approved for usage in ages **12 years and older**

## Dosage Form / Strength / Dosing

- **Dosage Form:** Tablet
  - Combination tablets
    - **elexacaftor 100mg + tezacaftor 50 mg + ivacaftor 75mg**
      - Orange, capsule/oval-shaped tablet, T100 embossed on it
    - **ivacaftor 150 mg**
      - Light blue, capsule/oval-shaped tablet, V150 printed in black ink on it
- **Dosing:** 12 Years and Older
  - 2 tablets in the morning and 12 hours later one in evening
  - **Morning tablets** contains
    - elexacaftor 100mg
    - tezacaftor 50mg
    - ivacaftor 75mg
  - **Evening tablet** is
    - ivacaftor 150mg
- **Dosing:** Hepatic Impaired
  - If **MODERATE** impairment there is **NO** evening ivacaftor dose
  - If **SEVERE** impairment patient cannot use
  - Otherwise normal dosing schedule
- **Dosing:** Patients on CYP3A Inhibitors
  - **MODERATE inhibitors:** No evening ivacaftor doses
    - **STRONG Inhibitors:** Morning doses every 48 hours (2 days) with **NO** evening ivacaftor doses
- **Missed doses:**
  - If **less than 6 hours** have passed take missed dose immediately then continue schedule
  - If **greater than 6 hours** have passed
    - If morning combination tablet was missed then take missed dose(s) and skip evening
    - If evening ivacaftor dose was missed, skip the dose



## Mechanism of Action & Pharmacology

- **elexacaftor + tezacaftor** bind to different CFTR protein sites. This additive effect aids in the increased cellular processing of F508del-CFTR substrate which increases the amount of CFTR proteins delivered to the cell surface.
- **ivacaftor** potentiates the channel opening of the CFTR proteins at the cell surface
- The combination of elexacaftor+tezacaftor+ivacaftor increases the function of the F508del-CFTR substrate at the cells surface which increases chloride transport.
- **Time to steady state:** elexacaftor w/in 14 days | tezacaftor w/in 8 days | ivacaftor w/in 3-5 days
- **Protein bound:** >99% | **Excretion:** **Primarily** fecally (72 to 87%)
- **Elimination:** elexacaftor – 1.18 L/hour | tezacaftor – 0.79 L/hour | ivacaftor – 10.2 L/hour

## Side Effects

- Headache, abdominal pain, diarrhea, rash

## Drug Interactions

- elexacaftor, tezacaftor, ivacaftor are **CYP3A substrates**
- CYP3A inducers such as rifampin, phenobarbital, carbamazepine, phenytoin, St. John's wort
- CYP3A inhibitors such as ketoconazole, itraconazole, clarithromycin
- ivacaftor is CYP2C9 inhibitor, caution warfarin

## Monitoring Parameters

- Liver function tests (ALT, AST, bilirubin)
  - Test **every 3 month** for 1<sup>st</sup> year, **then annually** after
  - Watch for elevated transaminases and bilirubin
  - Halt dosing if:
    - ALT or AST are >5 and the upper limit of normal (ULN)
    - Or ALT or AST > 3 and ULN with bilirubin >2 and ULN
    - Monitor tests until levels resolved
    - Consider risk/reward of resuming treatment

## Patient Counseling Information

- Tablets swallowed whole
- Taken with fat-containing food (cheeses, nuts, meats, or foods prepared with butter and oils)

## Reference(s)

- <https://www.drugs.com/pro/trikafta.html>

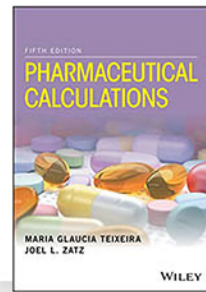


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## Comprehensive (NAPLEX)



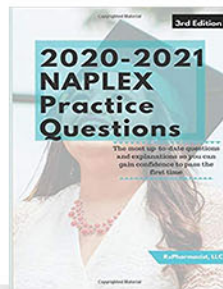
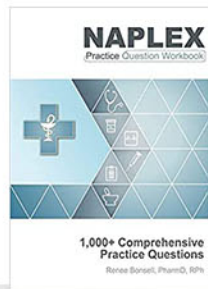
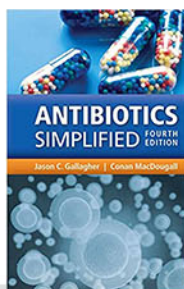
## Calculations (NAPLEX)



## Pharmacy Law (MPJE)



## Supplemental



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