MEDICATION GUIDE

TRIKAFTA® (tri-KAF-tuh)

(elexacaftor, tezacaftor, and ivacaftor tablets; ivacaftor tablets), co packaged for oral use
(elexacaftor, tezacaftor, and ivacaftor oral granules; ivacaftor oral granules), co-packaged

What is the most important information I should know about TRIKAFTA?

TRIKAFTA can cause serious liver damage and liver failure. Liver failure leading to transplantation and death have been seen in some people with or without a history of liver problems taking TRIKAFTA.

Your healthcare provider will do blood tests to check your liver:

- before you start TRIKAFTA
- then every month during your first 6 months of taking TRIKAFTA
- then every 3 months during the next 12 months of taking TRIKAFTA
- then at least every year while you are taking TRIKAFTA

Your healthcare provider may do blood tests to check the liver more often if you have had high liver enzymes in your blood in the past or are experiencing signs or symptoms of liver injury.

Stop taking TRIKAFTA and call your healthcare provider right away if you have any of the following symptoms of liver problems:

- pain, swelling, or discomfort in the upper right stomach (abdominal) area
- yellowing of your skin or the white part of your eyes
- mental changes
- nausea or vomiting
- dark, amber-colored urine
- loss of appetite
- have fluid in your stomach area (ascites)

What is TRIKAFTA?

- TRIKAFTA is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 2 years and older who have at least one copy of the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or another mutation that is responsive to treatment with TRIKAFTA.
- Talk to your healthcare provider to learn if you have an indicated CF gene mutation.

It is not known if TRIKAFTA is safe and effective in children under 2 years of age.

What should I tell my healthcare provider before taking TRIKAFTA?

Before taking TRIKAFTA, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had liver problems.
- are allergic to TRIKAFTA or any ingredients in TRIKAFTA. See the end of this medication guide for a complete list of ingredients in TRIKAFTA.
- have kidney problems.
- are pregnant or plan to become pregnant. It is not known if TRIKAFTA will harm your unborn baby. You and your healthcare provider should decide if you will take TRIKAFTA while you are pregnant.
- are breastfeeding or planning to breastfeed. It is not known if TRIKAFTA passes into your breast milk. You and your healthcare provider should decide if you will take TRIKAFTA while you are breastfeeding.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

TRIKAFTA may affect the way other medicines work and other medicines may affect how TRIKAFTA works.

The dose of TRIKAFTA may need to be adjusted when taken with certain medicines. Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure.

Especially tell your healthcare provider if you take:

- antibiotics such as rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines including ketoconazole, itraconazole (such as SPORANOX®), posaconazole (such as NOXAFIL®), voriconazole (such as VFEND®), or fluconazole (such as DIFLUCAN®).
- antibiotics including telithromycin, clarithromycin (such as BIAXIN®), or erythromycin (such as ERY-TAB®).

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take TRIKAFTA?

- Take TRIKAFTA exactly as your healthcare provider tells you to take it.
- Take TRIKAFTA by mouth only.
- TRIKAFTA consists of 2 different doses (a morning dose and an evening dose taken about **12** hours apart). Each dose has different ingredients.
- **Always take TRIKAFTA oral granules or tablets with food that contains fat**. Examples of fat-containing foods include butter, oil, eggs, peanut butter, nuts, meat, and whole-milk dairy products such as whole milk, cheese, and yogurt.
- TRIKAFTA oral granules (age 2 to less than 6 years weighing less than 31 pounds (14 kg)):
  - The white and blue packets each contain the medicines elexacaftor, tezacaftor, and ivacaftor. Take one morning dose packet in the morning.
  - The white and green color packets each contain the medicine ivacaftor. Take one evening dose packet in the evening.
- TRIKAFTA oral granules (age 2 to less than 6 years weighing 31 pounds (14 kg) or more):
  - The white and orange packets each contain the medicines elexacaftor, tezacaftor, and ivacaftor. Take one morning dose packet in the morning.
  - The white and pink color packets each contain the medicine ivacaftor. Take one evening dose packet in the evening.
- To prepare TRIKAFTA oral granules:
  - Hold the packet with the cut line on top.
  - Shake the packet gently to settle the TRIKAFTA oral granules.
  - Tear or cut the packet open along the cut line.
  - Carefully pour all the TRIKAFTA oral granules in the packet into 1 teaspoon (5 mL) of soft food or liquid in a small container (like an empty bowl). The food or liquid should be at or below room temperature. Some examples of soft foods or liquids include pureed fruits or vegetables, yogurt, applesauce, water, milk, or juice.
  - Mix the TRIKAFTA granules with food or liquid.
  - After mixing, give TRIKAFTA within 1 hour. Make sure all the medicine is taken.
- TRIKAFTA tablets (age 6 to less than 12 years weighing less than 66 pounds (30 kg)):
  - The light orange tablet is marked with 'T50' and each tablet contains the medicines elexacaftor, tezacaftor and ivacaftor. Take 2 light orange tablets in the morning.
  - The light blue tablet is marked with 'V 75' and contains the medicine ivacaftor. Take 1 light blue tablet in the evening.
- TRIKAFTA tablets (age 6 to less than 12 years weighing 66 pounds (30 kg) or more, and age 12 years and older):
  - The orange tablet is marked with 'T100' and each tablet contains the medicines elexacaftor, tezacaftor and ivacaftor. Take 2 orange tablets in the morning.
  - The light blue tablet is marked with 'V 150' and contains the medicine ivacaftor. Take 1 light blue tablet in the evening.

- Take TRIKAFTA tablets whole.
- If you miss a dose of TRIKAFTA and:
  - it is **6 hours or less** from the time you usually take the morning dose or the evening dose, **take the missed dose** with food that contains fat as soon as you can. Then take your next dose at your usual time.
  - it is **more than 6 hours** from the time you usually take the morning dose, **take the missed dose** with food that contains fat as soon as you can. **Do not take the evening dose**.
  - it is **more than 6 hours** from the time you usually take the evening dose, **do not take the missed dose**. Take your next morning dose at the usual time with food that contains fat.
  - **Do not** take more than your usual dose of TRIKAFTA to make up for a missed dose.
  - **Do not** take the morning and evening doses at the same time.
- If you have liver problems, your healthcare provider may tell you to take TRIKAFTA differently.

If you are not sure about your dosing, call your healthcare provider.

What should I avoid while taking TRIKAFTA?

Avoid food or drink that contains grapefruit while you are taking TRIKAFTA.

What are the possible or reasonably likely side effects of TRIKAFTA?

TRIKAFTA can cause serious side effects, including:

- **See "What is the most important information I should know about TRIKAFTA?"**
- **Serious Allergic Reactions** can happen to people who are treated with TRIKAFTA. Call your healthcare provider or go to the emergency room right away if you have any symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - swelling of the face, lips and/or tongue, difficulty swallowing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract)** has happened in some children and adolescents treated with TRIKAFTA. If you are a child or adolescent, your healthcare provider should perform eye examinations before and during treatment with TRIKAFTA to look for cataracts.

The most common side effects of TRIKAFTA include:

- headache
- upper respiratory tract infection (common cold) including stuffy and runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- increase in liver enzymes
- increase in a certain blood enzyme called creatine phosphokinase
- flu (influenza)
- inflamed sinuses
- increase in blood bilirubin
- constipation

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.
These are not all the possible side effects of TRIKAFTA. For more information, ask your healthcare provider or pharmacist.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store TRIKAFTA?

- Store TRIKAFTA at room temperature between 68ºF to 77ºF (20ºC to 25ºC).

Keep TRIKAFTA and all medicines out of the reach of children.

General information about the safe and effective use of TRIKAFTA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TRIKAFTA for a condition for which it was not prescribed. Do not give TRIKAFTA to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about TRIKAFTA that is written for health professionals.

What are the ingredients in TRIKAFTA?

Elexacaftor/tezacaftor/ivacaftor tablets:

Active ingredients: elexacaftor, tezacaftor and ivacaftor.

Inactive ingredients: croscarmellose sodium, hypromellose, hypromellose acetate succinate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate. The tablet film coat contains hydroxypropyl cellulose, hypromellose, iron oxide red, iron oxide yellow, talc, and titanium dioxide.

Ivacaftor tablets:

Active ingredients: ivacaftor.

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, hypromellose acetate succinate, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and sodium lauryl sulfate.

The tablet film coat contains carnauba wax, FD&C Blue #2, PEG 3350, polyvinyl alcohol, talc, and titanium oxide.

The printing ink contains ammonium hydroxide, iron oxide black, propylene glycol, and shellac.

Elexacaftor/tezacaftor/ivacaftor oral granules:

Active ingredients: elexacaftor, tezacaftor, and ivacaftor.

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, hypromellose, hypromellose acetate succinate, lactose monohydrate, magnesium stearate, mannitol, sodium lauryl sulfate, and sucralose.

Ivacaftor oral granules:

Active ingredients: ivacaftor.

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, hypromellose acetate succinate, lactose monohydrate, magnesium stearate, mannitol, sodium lauryl sulfate, and sucralose.

VERTEX

Manufactured for: Vertex Pharmaceuticals Incorporated; 50 Northern Avenue, Boston, MA 02210

For more information, go to www.trikafta.com or call 1-877-752-5933.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Approved: 12/2024