What is TRIKAFTA® (elexacaftor/tezacaftor/ivacaftor and ivacaftor)?

TRIKAFTA is a prescription medicine used for the treatment of cystic fibrosis (CF) in patients aged 12 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 doctor to learn if you have an indicated CF gene mutation.

It is not known if TRIKAFTA is safe and effective in children under 12 years of age.

Please see Important Safety Information for TRIKAFTA on pages 5-6 and full Prescribing Information, including Patient Information.
How does TRIKAFTA work?
Please see Important Safety Information for TRIKAFTA on pages 5-6 and full Prescribing Information, including Patient Information.
**WHO IS TRIKAFTA® FOR?**

More people are now eligible for TRIKAFTA

You may be eligible if you have CF and are 12 years and older with **at least one** F508del mutation or **at least one** other newly approved mutation that is responsive to TRIKAFTA*.

*Predicted to respond to TRIKAFTA based on results in a laboratory setting. Not clinically evaluated.

For the complete list of responsive mutations, visit TRIKAFTAEligibility.com or see the full Prescribing Information.
The underlying cause

CF is caused by mutations in the CF gene. These mutations lead to defects in a specific protein called the cystic fibrosis transmembrane conductance regulator (CFTR) protein. As a result of these defects, the CFTR proteins don’t work the way they should.

**CF gene mutations cause one or both defects illustrated below:**

Because of these defects, chloride ions cannot move into or out of the cells like they should. This can cause thick, sticky mucus to build up in organs, such as the lungs.

**Trikafta: Three components that work together to target the underlying cause**

Trikafta adds **elexacaftor** to **tezacaftor** and **ivacaftor** to target CFTR protein defects caused by the F508del mutation or another mutation responsive to Trikafta.

What is known about how Trikafta works was learned from studies conducted in a laboratory. Keep in mind that results from laboratory studies do not always match how these medicines work in a person. If you have questions about your treatment, speak with your healthcare provider.
WHAT IS THE IMPORTANT SAFETY INFORMATION?

Who should not take TRIKAFTA®?

Do not take TRIKAFTA if you take certain medicines such as:

- 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

Talk to your doctor before taking TRIKAFTA if you take any of the medicines or herbal supplements listed above.

What should I tell my doctor about my medical conditions before starting TRIKAFTA?

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

- have kidney problems
- have or have had liver problems
- are pregnant or plan to become pregnant. It is not known if TRIKAFTA will harm your unborn baby.
  You and your doctor 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 doctor should decide if you will take TRIKAFTA while you are breastfeeding

Are there any other medicines that may interact with TRIKAFTA?

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

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. The dose of TRIKAFTA may need to be adjusted when taken with certain medicines.

Ask your doctor or pharmacist for a list of these medicines if you are not sure. Make sure the list includes medicines from all your pharmacies, if you have more than one.

Especially tell your doctor if you take:

- antifungal medicines including ketoconazole (such as NIZORAL®), itraconazole (such as SPORANOX®), posaconazole (such as NOXAFIL®), voriconazole (such as VFEND®), or fluconazole (such as DIFLUCAN®)
- antibiotics including telithromycin (such as KETEK®), clarithromycin (such as BIAXIN®), or erythromycin (such as ERY-TAB®)
- other medicines including rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John's wort

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

What should I avoid while taking TRIKAFTA?

- TRIKAFTA can cause dizziness in some people who take it. Do not drive a car, use machinery, or do anything that needs you to be alert until you know how TRIKAFTA affects you
- Avoid food or drink that contains grapefruit while you are taking TRIKAFTA
WHAT IS THE IMPORTANT SAFETY INFORMATION? (Continued)

What are the possible side effects of TRIKAFTA®?

TRIKAFTA can cause serious side effects, including:

- **High liver enzymes in the blood** is a common side effect in people treated with TRIKAFTA. These can be serious and may be a sign of liver injury. Your doctor will do blood tests to check your liver:
  - before you start TRIKAFTA
  - every 3 months during your first year of taking TRIKAFTA
  - every year while you are taking TRIKAFTA

Your doctor may do blood tests to check the liver more often if you have had high liver enzymes in your blood in the past.

Call your doctor right away if you have any of the following symptoms of liver problems:
- pain or discomfort in the upper right stomach (abdominal) area
- yellowing of your skin or the white part of your eyes
- loss of appetite

**Abnormality of the eye lens (cataract)** in some children and adolescents treated with TRIKAFTA. If you are a child or adolescent, your doctor should perform eye examinations before and during treatment with TRIKAFTA to look for cataracts

Your healthcare provider will monitor you for side effects. Be sure to call your healthcare provider if you have any questions.

What were the most common side effects seen with TRIKAFTA?

This information is based on what was reported in a study of people age 12 years and older with one copy of the F508del mutation and another mutation defined in the study*.

<table>
<thead>
<tr>
<th>Side effect</th>
<th>TRIKAFTA (n=202)</th>
<th>Placebo (n=201)</th>
<th>Side effect</th>
<th>TRIKAFTA (n=202)</th>
<th>Placebo (n=201)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>17%</td>
<td>15%</td>
<td>Increase in a blood enzyme called creatine phosphokinase (CPK)†</td>
<td>9%</td>
<td>4%</td>
</tr>
<tr>
<td>Upper respiratory tract infection (common cold)</td>
<td>16%</td>
<td>12%</td>
<td>Increase in a liver enzyme called aspartate aminotransferase (AST)†</td>
<td>9%</td>
<td>2%</td>
</tr>
<tr>
<td>Stomach (abdominal) pain</td>
<td>14%</td>
<td>9%</td>
<td>Runny nose</td>
<td>8%</td>
<td>3%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>13%</td>
<td>7%</td>
<td>Stuffy nose</td>
<td>7%</td>
<td>5%</td>
</tr>
<tr>
<td>Rash</td>
<td>10%</td>
<td>5%</td>
<td>Flu (influenza)</td>
<td>7%</td>
<td>1%</td>
</tr>
<tr>
<td>Increase in a liver enzyme called alanine aminotransferase (ALT)†</td>
<td>10%</td>
<td>3%</td>
<td>Inflamed sinuses</td>
<td>5%</td>
<td>4%</td>
</tr>
<tr>
<td>Nasal congestion</td>
<td>9%</td>
<td>7%</td>
<td>Increase in blood bilirubin†</td>
<td>5%</td>
<td>1%</td>
</tr>
</tbody>
</table>

*These are not all the possible side effects of TRIKAFTA. Call your doctor for medical advice about side effects. You are encouraged to report side effects to FDA at 1-800-FDA-1088.

†Mutations that either do not make a CFTR protein or make a protein that tezacaftor and/or ivacaftor cannot act on.
‡Elevated levels of these blood tests could mean there is liver irritation or injury.
¶This enzyme is measured to help determine if there has been irritation to muscles.

Please see additional Important Safety Information for TRIKAFTA on page 5 and full Prescribing Information, including Patient Information.
Study details: People age 12+ with F508del and a mutation defined in the study

This study was designed to determine the possible benefits and risks of TRIKAFTA compared with placebo. All people in this study had one copy of the F508del mutation. “A mutation defined in the study” refers to mutations that either do not make a CFTR protein or make a protein that tezacaftor and/or ivacaftor cannot act on.

403 people with CF, 12 years and older, with one copy of the F508del mutation and a mutation defined in the study, participated in the 24-week study.

200 took TRIKAFTA with fat-containing food.
Two tablets, each containing elixacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg in the morning and 1 tablet containing ivacaftor 150 mg in the evening about 12 hours later.

203 took placebo twice daily with fat-containing food about 12 hours apart.

All participants continued to take their other prescribed CF therapies.

Please see Important Safety Information for TRIKAFTA on pages 5-6 and full Prescribing Information, including Patient Information.
The study results of TRIKAFTA are an average of all people studied and differed among individuals. Your experience may be different.

*FEV₁=forced expiratory volume, or how much air a person can exhale in a forced breath in 1 second.
Decrease in sweat chloride

**Significant decrease of 41.2 mmol/L** on average compared with placebo at 4 weeks. Results were maintained throughout the study, with a decrease of **41.8 mmol/L** on average compared with placebo through 24 weeks.

People with CF have high sweat chloride, which is the amount of salt in your sweat. On average, people taking TRIKAFTA started the study with a sweat chloride level of 102.3 mmol/L.

The study results of TRIKAFTA are an average of all people studied and differed among individuals. Your experience may be different.

Fewer pulmonary exacerbations

Through **24 weeks**, the number of pulmonary exacerbations **significantly decreased by 63%** for people taking TRIKAFTA® compared with placebo.

There were **41 pulmonary exacerbations** in the TRIKAFTA group and **113 in the placebo group**.

Pulmonary exacerbations are changes in certain symptoms that require treatment with new oral, intravenous (IV), or inhaled antibiotics.

**Additional pulmonary exacerbation results**

- **71% fewer pulmonary exacerbations** that led to hospitalizations through 24 weeks.
  - 9 in the TRIKAFTA group and 32 in the placebo group

- **78% fewer pulmonary exacerbations** that led to IV antibiotics through 24 weeks.
  - 11 in the TRIKAFTA group and 51 in the placebo group

This study was not designed to determine whether these changes were because of TRIKAFTA. These additional results are not included in the full Prescribing Information for TRIKAFTA.
Improvement in CF respiratory symptoms

People taking TRIKAFTA® reported a significant 20.1-point average increase in CF respiratory symptom score compared with placebo at 4 weeks. Results were maintained throughout the study, with an increase of 20.2 points on average compared with placebo through 24 weeks.

The average increase across all symptoms does not mean there was an improvement in each symptom measured.

Respiratory symptoms were measured using a tool called the Cystic Fibrosis Questionnaire-Revised Respiratory Domain score.

On average, people taking TRIKAFTA began the study with a score of 68.3 points.

Increase in body mass index (BMI)*

Significant BMI increase of 1 kg/m² on average compared with placebo at 24 weeks.

For example, a person who is 5’5” and weighs 130 pounds would gain about 6 pounds on average at 24 weeks.

*BMI=a measure of someone's weight in relation to his or her height.

The study results of TRIKAFTA are an average of all people studied and differed among individuals. Your experience may be different.
Study details: People age 12+ with F508del/F508del

This study was designed to determine the possible benefits and risks of TRIKAFTA compared with SYMDEKO® (tezacaftor/ivacaftor and ivacaftor), a prescription medicine used for the treatment of people with CF with two F508del mutations.

**107 people with CF, 12 years and older, with two copies of the F508del mutation, participated in the study.**

For the first 4 weeks, everyone took SYMDEKO. Then, participants were randomly split into 2 groups:

- **55 switched to TRIKAFTA for 4 weeks. Participants took TRIKAFTA with fat-containing food.**
  
  Two tablets, each containing elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg in the morning and 1 tablet containing ivacaftor 150 mg in the evening about 12 hours later

- **52 continued taking SYMDEKO for 4 more weeks. Participants took SYMDEKO with fat-containing food.**
  
  One tablet containing tezacaftor 100 mg/ivacaftor 150 mg in the morning and one tablet containing ivacaftor 150 mg in the evening about 12 hours later

All participants discontinued any previous CFTR modulators but continued to take their other prescribed CF therapies.

Please see Important Safety Information on pages 5-6 for TRIKAFTA and on pages 17-18 for SYMDEKO. Please see TRIKAFTA full Prescribing Information, including Patient Information. Please see SYMDEKO full Prescribing Information, including Patient Information.
The study results of TRIKAFTA are an average of all people studied and differed among individuals. Your experience may be different.

*FEV₁=forced expiratory volume, or how much air a person can exhale in a forced breath in 1 second.
Decrease in sweat chloride

**Significant decrease of 45.1 mmol/L** on average compared with SYMDEKO® (tezacaftor/ivacaftor and ivacaftor) at 4 weeks.

People with CF have high sweat chloride, which is the amount of salt in your sweat. On average, people taking TRIKAFTA® started the study with a sweat chloride level of 91.4 mmol/L.

Improvement in CF respiratory symptoms

People taking TRIKAFTA reported a **significant 17.4-point average increase** in CF respiratory symptom score compared with SYMDEKO at 4 weeks.

The average increase across all symptoms does not mean there was an improvement in each symptom measured.

Respiratory symptoms were measured using a tool called the Cystic Fibrosis Questionnaire-Revised Respiratory Domain score.

On average, people taking TRIKAFTA began the study with a score of 70.6 points.

The study results of TRIKAFTA are an average of all people studied and differed among individuals. Your experience may be different.
How is TRIKAFTA packaged?

- Each box of TRIKAFTA has 4 weekly blister cards
- Each blister card contains 21 tablets: 2 for each morning (orange), and 1 for each evening (light blue)

Talk to your healthcare provider about all of the medicines you take, as your dose of TRIKAFTA may need to be adjusted.

It’s important to take TRIKAFTA, along with your other CF therapies, exactly as your healthcare provider tells you.
**HOW DO I TAKE TRIKAFTA®?**

**What is the recommended dose?**

- Take **2 orange tablets** in the morning with fat-containing food.
- About **12 hours later**.
- Take **1 light blue tablet** in the evening with fat-containing food.

**Each dose must be taken with fat-containing food:**
- Always take TRIKAFTA with a meal or snack that contains fat to help your body absorb the medicine.
- Examples of fat-containing foods include butter, peanut butter, eggs, nuts, meat, and whole-milk dairy products such as whole milk, cheese, and yogurt.

**Every dose matters**

Make sure to take every dose of TRIKAFTA exactly as prescribed by your healthcare provider. Because the 3 components of TRIKAFTA work together to treat the underlying cause, each and every dose matters.

Avoid foods and drinks that contain grapefruit while taking TRIKAFTA because they may affect the amount of TRIKAFTA in the body.

**GET DELICIOUS RECIPES AND FOOD IDEAS**

VISIT CF KITCHEN ON EVERYDAY-CF.COM

- Filter recipes by type of meal and level of difficulty
- Find ways to take recipes to the next level
- Explore fresh tips for when you’re on the go

Everyday CF

Your source for fresh insights, resources, and tips for supporting your life with CF.

Please see **Important Safety Information** for TRIKAFTA on pages 5-6 and full Prescribing Information, including **Patient Information**.
I MISSED A DOSE—WHAT SHOULD I DO?

What to do if you miss an AM dose

- **If it’s been 6 hours or LESS since you missed your usual AM dose**
  - Take the missed dose with fat-containing food as soon as you can.
  - Then take your next dose at your usual time with fat-containing food.

- **If it’s been MORE than 6 hours since you missed your usual AM dose**
  - Take the missed dose with fat-containing food as soon as you can.
  - Then **do not** take the light blue tablet in the evening. Resume regular dosing schedule the next day.

What to do if you miss a PM dose

- **If it’s been 6 hours or LESS since you missed your usual PM dose**
  - Take the missed dose with fat-containing food as soon as you can.
  - Then take your next dose at your usual time with fat-containing food.

- **If it’s been MORE than 6 hours since you missed your usual PM dose**
  - **Do not** take the missed dose.
  - Take your next dose at the usual time with fat-containing food.

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*Do not take more than your usual dose of TRIKAFTA® to make up for a missed dose.*

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Please see **Important Safety Information** for TRIKAFTA on pages 5-6 and **full Prescribing Information**, including **Patient Information**.
What is SYMDEKO?

SYMDEKO is a prescription medicine used for the treatment of cystic fibrosis (CF) in patients age 6 years and older who have two copies of the F508del mutation, or who have at least one mutation in the CF gene that is responsive to treatment with SYMDEKO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if SYMDEKO is safe and effective in children under 6 years of age.

Important Safety Information

Do not take SYMDEKO if you take certain medicines or herbal supplements such as:

- 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

Talk to your doctor before taking SYMDEKO if you take any of the medicines or herbal supplements listed above.

Before taking SYMDEKO, tell your doctor about all of your medical conditions, including if you:

- have or have had liver problems
- have kidney problems
- are pregnant or plan to become pregnant. It is not known if SYMDEKO will harm your unborn baby. You and your doctor should decide if you will take SYMDEKO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if SYMDEKO passes into your breast milk. You and your doctor should decide if you will take SYMDEKO while you are breastfeeding

SYMDEKO may affect the way other medicines work, and other medicines may affect how SYMDEKO works.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements, because the dose of SYMDEKO may need to be adjusted when taken with certain medicines.

Especially tell your doctor if you take:

- antifungal medicines such as ketoconazole (e.g., NIZORAL®),itraconazole (e.g., SPORANOX®), posaconazole (e.g., NOXAFIL®), voriconazole (e.g., VFEND®), or fluconazole (e.g., DIFLUCAN®)
- antibiotics such as telithromycin (e.g., KETEK®), clarithromycin (e.g., BIAXIN®), or erythromycin (e.g., ERY-TAB®)

What should I avoid while taking SYMDEKO?

- SYMDEKO can cause dizziness in some people who take it. Do not drive a car, use machinery, or do anything that needs you to be alert until you know how SYMDEKO affects you
- Avoid food or drink that contains grapefruit while you are taking SYMDEKO

Please see additional Important Safety information for SYMDEKO on page 18, and Important Safety Information for TRIKAFTA on pages 5-6. Please see TRIKAFTA full Prescribing Information, including Patient Information. Please see SYMDEKO full Prescribing Information, including Patient Information.
Important Safety Information for SYMDEKO® (continued)

What are the possible side effects of SYMDEKO?

SYMDEKO can cause serious side effects, including:

- **High liver enzymes in the blood** have been reported in people treated with SYMDEKO or treated with ivacaftor alone. Your doctor will do blood tests to check your liver:
  - before you start SYMDEKO
  - every 3 months during your first year of taking SYMDEKO
  - every year while you are taking SYMDEKO

Your doctor may do blood tests to check the liver more often if you have had high liver enzymes in your blood in the past.

Call your doctor right away if you have any of the following symptoms of liver problems:

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

- **Abnormality of the eye lens (cataract)** in some children and adolescents treated with SYMDEKO or with ivacaftor alone. If you are a child or adolescent, your doctor should perform eye examinations before and during treatment with SYMDEKO to look for cataracts

The most common side effects of SYMDEKO include headache, nausea, sinus congestion, and dizziness.

These are not all the possible side effects of SYMDEKO. Call your doctor for medical advice about side effects. You are encouraged to report side effects to FDA at 1-800-FDA-1088.
Your dedicated Patient Support Specialist can help by:

- **Verifying coverage with your insurance company** to review your coverage and out-of-pocket costs.

- **Connecting with your healthcare provider** to discuss any prior authorization (PA) requirements or questions your insurance company may have while determining your coverage.

- **Providing financial assistance information.** If you have commercial insurance, Vertex may be able to help reduce your co-payment obligation to as little as $15 per refill*. Call your Patient Support Specialist at **1-877-752-5933 (press 2)** to see if you’re eligible.
  *Limitations apply, and Vertex reserves the right to rescind, revoke, or amend this assistance program at any time.

- **Working with your specialty pharmacy** to help you coordinate shipments and let you know when it’s time to refill your Vertex medicine.

- **Continuing to support you** while you are taking a Vertex medicine by providing educational tools, text message refill reminders, and other helpful resources.

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**Not enrolled in Vertex GPS?**

If you have been prescribed TRIKAFTA® (elexacaftor/tezacaftor/ivacaftor and ivacaftor), ask your healthcare provider about completing an enrollment form at your next appointment.

**Already enrolled?**

If you are currently enrolled in GPS, you can call or text your Patient Support Specialist at **1-877-752-5933 (press 2)**, Monday through Friday, from 8:30 AM to 7 PM ET.

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Learn more about GPS and the support resources available at [VertexGPS.com](http://VertexGPS.com).
**A breakthrough treatment for people with CF age 12 years and older with at least one copy of the F508del mutation or another responsive mutation**

The benefits and risks of TRIKAFTA were evaluated in 2 studies. One study compared TRIKAFTA with placebo in people with F508del and another mutation defined in the study*. The other study was in people with two F508del mutations and compared TRIKAFTA with SYMDEKO (tezacaftor/ivacaftor and ivacaftor), a prescription medicine used for the treatment of people with CF with two F508del mutations.

<table>
<thead>
<tr>
<th>On average, people taking TRIKAFTA experienced:</th>
<th>24-week study of F508del/ a mutation defined in the study</th>
<th>4-week study of F508del/F508del</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improvement in lung function (FEV1)</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>FEV1=forced expiratory volume, or how much air a person can exhale in a forced breath in 1 second</td>
<td></td>
<td></td>
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<tr>
<td>Fewer pulmonary exacerbations</td>
<td>●</td>
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<td>Pulmonary exacerbations are changes in certain symptoms that require treatment with new oral, IV, or inhaled antibiotics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decrease in sweat chloride</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Measured through a sweat test that determines the amount of salt in your sweat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reduction in CF respiratory symptoms</td>
<td>●</td>
<td>●</td>
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<td>Respiratory symptoms were measured using a tool called the Cystic Fibrosis Questionnaire-Revised Respiratory Domain score</td>
<td></td>
<td></td>
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<td>Increase in body mass index (BMI)</td>
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**Important Safety Information**

**Do not take TRIKAFTA if you take certain medicines such as:**

- 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

Talk to your doctor before taking TRIKAFTA if you take any of the medicines or herbal supplements listed above.

**Additional Safety Information**

TRIKAFTA can cause serious side effects, including high liver enzymes in the blood and abnormality of the eye lens (cataract).

To learn more about the studies’ designs and results, see pages 7 through 13.

*Mutations that either do not make a CFTR protein or make a protein that tezacaftor and/or ivacaftor cannot act on.

Please see additional Important Safety Information on pages 5-6 for TRIKAFTA and Important Safety Information on pages 17-18 for SYMDEKO. Please see TRIKAFTA full Prescribing Information, including Patient Information. Please see SYMDEKO full Prescribing Information, including Patient Information.

To learn more, talk to your healthcare provider and visit TRIKAFTA.com.