

(elexacaftor/tezacaftor/ivacaftor and ivacaftor)

100 mg/50 mg/75 mg and 75 mg oral granules



& the Musical Playground



Read this story with your loved one to get into the groove of their TRIKAFTA® routine





copy of the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or another mutation that is responsive to treatment with TRIKAFTA.

indicated CF gene mutation.

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

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

- are allergic to TRIKAFTA or any ingredients in TRIKAFTA. See the Patient Information for a list of ingredients

- 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.
- TRIKAFTA while you are breastfeeding









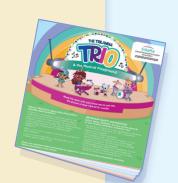




A note for caregivers

This book is for caregivers of children with cystic fibrosis (CF) age 2 through 5 years with certain mutations who have been prescribed TRIKAFTA® by their healthcare provider.

Read it together to help your loved one become more involved in their treatment routine, and find the link at the end to hear the Trilandia Trio perform!



For details on giving TRIKAFTA to your loved one, visit **HowToTakeTRIKAFTA.com**.

IMPORTANT SAFETY INFORMATION (Continued)

Tell your doctor 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 doctor or pharmacist for a list of these medicines if you are not sure.





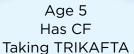


Age 2 Has CF Taking TRIKAFTA®















Age 4 Doesn't have CF Supportive brother

Now that you've met the Trio, let's start the story!



The Trio's puppy pal

IMPORTANT SAFETY INFORMATION (Continued)

Tell your doctor about all the medicines you take (continued).

Especially tell your doctor 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



Please see <u>Important Safety Information</u> and <u>full Prescribing Information</u>, including <u>Patient Information</u>.



Then Dr. Lori called to share **some wonderful news**

About a CF medicine for certain kids as young as two.





IMPORTANT SAFETY INFORMATION (Continued)

Tell your doctor about all the medicines you take (continued).

Especially tell your doctor if you take (continued):

- 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®)



"It's time to celebrate!" said Dad. "Let's head on **down the slide**.

Some really fun things for you to see are on the other side."



IMPORTANT SAFETY INFORMATION (Continued)

What should I avoid while taking TRIKAFTA®?

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



What are the possible side effects of TRIKAFTA®?

TRIKAFTA can cause serious side effects, including:

• **Liver damage and worsening of liver function** in people with severe liver disease that can be serious and may require transplantation. Liver damage has also happened in people without liver disease





Please see <u>Important Safety Information</u> and <u>full Prescribing Information</u>, including <u>Patient Information</u>.



What are the possible side effects of TRIKAFTA® (continued)?

TRIKAFTA can cause serious side effects, including (continued):

- **High liver enzymes in the blood,** which 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 year while you are taking TRIKAFTA
- every 3 months during your first year of 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.



What are the possible side effects of TRIKAFTA® (continued)?

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

- o 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
- o dark, amber-colored urine





As Zac got on the seesaw, it screeched down to one side.

But after that **it wouldn't budge**, however hard he tried.



IMPORTANT SAFETY INFORMATION (Continued)

What are the possible side effects of TRIKAFTA® (continued)?

TRIKAFTA can cause serious side effects, including (continued):

- Serious allergic reactions have happened 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, or difficulty swallowing
- o light-headedness or dizziness



Ivy came along to help, then Mom, Dad, and his brother.

"Let's sit together," said Zac,
"we'll balance out each other."







What are the possible side effects of TRIKAFTA® (continued)?

TRIKAFTA can cause serious side effects, including (continued):

Abnormality of the eye lens (cataract), which has happened 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



Now that the Trio has learned a thing or two, it's time to put it all together—assemble the crew!

They jumped up on stage to play their new hit song. So **why not join in?** It's fun to sing along!





called creatine phosphokinase

stomach (abdominal) pain

After their adventures, the Trio had returned

Just in time for dinner, to share what they had learned.





IMPORTANT SAFETY INFORMATION (Continued)

What are the possible side effects of TRIKAFTA® (continued)?

Tell your doctor 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 doctor or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.





IMPORTANT SAFETY INFORMATION



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:



are allergic to TRIKAFTA or any ingredients in TRIKAFTA. See the Patient Information for a list of ingredients



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





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Please see additional <u>Important Safety Information</u> and <u>full Prescribing Information</u>, including <u>Patient Information</u>.





Are there any other medicines that may interact with TRIKAFTA®?



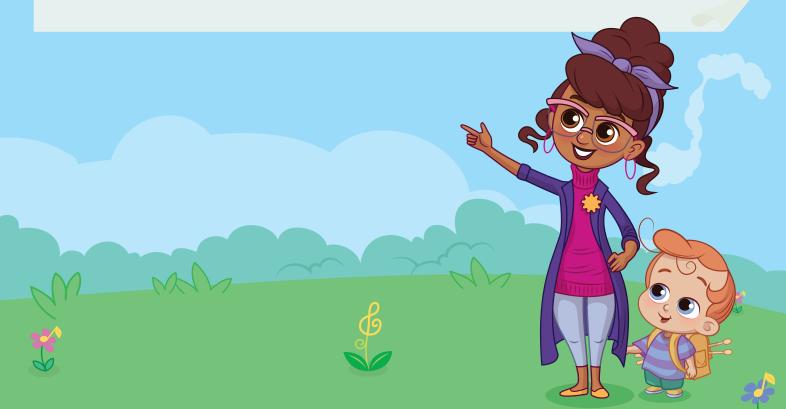
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TRIKAFTA may affect the way other medicines work, and other medicines may affect how TRIKAFTA works. The dose of TRIKAFTA may need to be adjusted when taken with certain medicines. Ask your doctor or pharmacist for a list of these medicines if you are not sure.



Especially tell your doctor 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®)
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What should I avoid while taking TRIKAFTA®?

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



What are the possible side effects of TRIKAFTA?

TRIKAFTA can cause serious side effects, including:

- Liver damage and worsening of liver function in people with severe liver disease that can be serious and may require transplantation. Liver damage has also happened in people without liver disease
- · High liver enzymes in the blood, which 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:
 - TRIKAFTA
 - before you start
 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
- nausea or vomiting
- o dark, amber-colored urine
- Serious allergic reactions have happened 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:
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 - tightness of the chest or throat or difficulty breathing
- swelling of the face, lips, and/or tongue, or difficulty swallowing
- light-headedness or dizziness
- Abnormality of the eye lens (cataract), which has happened 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













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IMPORTANT SAFETY INFORMATION (Continued)

What were the most common side effects seen with TRIKAFTA®?

The most common side effects of TRIKAFTA include:

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

Tell your doctor 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 doctor or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.





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