



symdeko[®]
(tezacaftor/ivacaftor
and ivacaftor)
100/150 mg and 150 mg tablets
50/75 mg and 75 mg tablets



SYMDEKO[®] WORKS ON TREATING THE UNDERLYING CAUSE.

The sooner you or your child gets started,
the sooner SYMDEKO can get to work.

WHAT IS SYMDEKO[®] (tezacaftor/ivacaftor and ivacaftor)?

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.

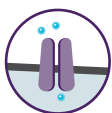
It is not known if SYMDEKO is safe and effective in children under 6 years of age.

Please see Important Safety Information on pages 9-12 and full Prescribing Information, including Patient Information.



EVERYONE'S CF IS DIFFERENT,

But ultimately, CF is always working beneath the surface.



SINCE CF IS ALWAYS WORKING BENEATH THE SURFACE,

Your or your child's treatment should be, too.



SYMDEKO IS TOUGH ON CF,

Because it targets the underlying cause in people age 6 years and older with eligible mutations.

Start learning about SYMDEKO, a medicine from Vertex for people with CF age 6 years and older with 2 copies of the F508del mutation, or who have at least 1 mutation in the CF gene that is responsive to treatment with SYMDEKO.

View the complete list of responsive mutations at [SYMDEKO.com/eligibility](https://www.symdeko.com/eligibility) or talk to your healthcare provider to ask if SYMDEKO could be an option for you.

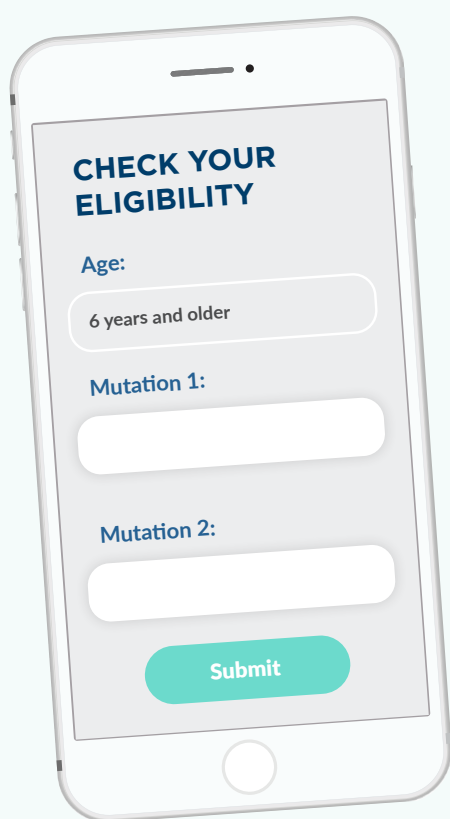
IMPORTANT SAFETY INFORMATION

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

- have or have had liver problems
- are allergic to SYMDEKO or any ingredients in SYMDEKO. See the Patient Information for a list of ingredients
- 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

Please see additional Important Safety Information on pages 9-12 and full Prescribing Information, including Patient Information.

SYMDEKO is for the treatment of 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.



**VISIT [SYMDEKO.COM/ELIGIBILITY](https://symdeko.com/eligibility)
TO SEE IF YOU'RE ELIGIBLE
IN 3 EASY STEPS:**

STEP 1:

Enter your mutations.

STEP 2:

Hit "Submit."

STEP 3:

Discuss your results with your healthcare provider.

IMPORTANT SAFETY INFORMATION

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

SYMDEKO may affect the way other medicines work and other medicines may affect how SYMDEKO works. The dose of SYMDEKO 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.

Please see additional Important Safety Information on pages 9-12 and full Prescribing Information, including Patient Information.

CLICK BELOW TO GET THE INFORMATION YOU'RE LOOKING FOR

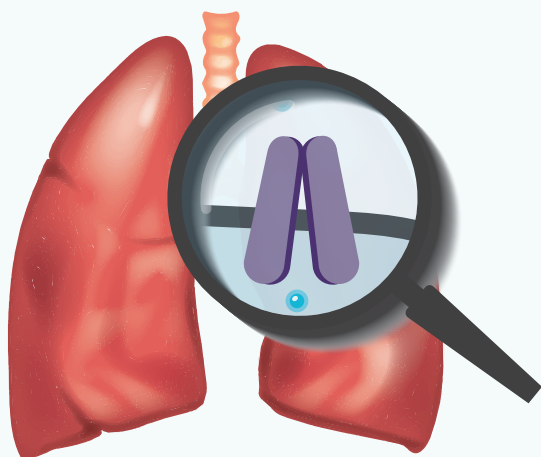
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IMPORTANT SAFETY INFORMATION

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 such as ketoconazole, itraconazole (such as SPORANOX®), posaconazole (such as NOXAFIL®), voriconazole (such as VFEND®), or fluconazole (such as DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (such as BIAxin®), or erythromycin (such as ERY-TAB®)

Please see additional [Important Safety Information](#) on pages 9-12 and [full Prescribing Information](#), including [Patient Information](#).



THE UNDERLYING CAUSE OF CF

CF is caused by CFTR protein defects. A mutation in the genes of a person with CF may make defective CFTR proteins that:

- Don't open correctly
- Don't get to the cell surface, where they are normally located

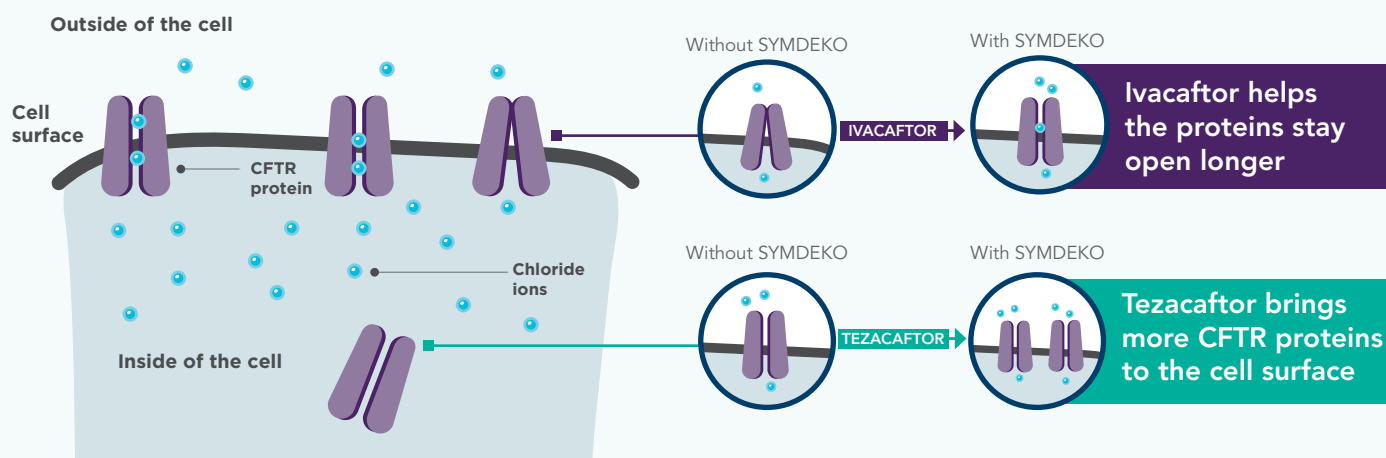
A person with CF may make CFTR proteins that have one or both of these defects.



Because of these defects, chloride ions cannot flow freely into or out of the cells as they should. This can lead to thick, sticky mucus in the lungs.

SYMDEKO TARGETS THE UNDERLYING CAUSE

SYMDEKO is made up of tezacaftor and ivacaftor, which work on certain defects of the CFTR protein at the cellular level in patients age 6 years and older with eligible mutations.











Together, tezacaftor and ivacaftor help certain CFTR proteins work better. This allows more chloride ions to pass into and out of the cells—helping keep a balance of salt and water in certain organs, such as the lungs.

What is known about how SYMDEKO 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.

TAKING SYMDEKO

It's important to take SYMDEKO exactly as your healthcare provider tells you to take it, along with your or your child's other CF therapies. SYMDEKO should always be taken by mouth, along with fat-containing food.

The recommended dose of SYMDEKO is:

AGE/WEIGHT	DOSE	
	 Morning	 Evening
For children age 6 through 11 years weighing <~66 lbs (less than 30 kg)	 One white tablet (tezacaftor 50 mg/ivacaftor 75 mg)	 One light blue tablet (ivacaftor 75 mg)
For children age 6 through 11 years weighing ≥~66 lbs (30 kg or more)	 One yellow tablet (tezacaftor 100 mg/ivacaftor 150 mg)	 One light blue tablet (ivacaftor 150 mg)
For people age 12 years and older	 One yellow tablet (tezacaftor 100 mg/ivacaftor 150 mg)	 One light blue tablet (ivacaftor 150 mg)




For children age 6 through 11 years weighing less than ~66 pounds



For children age 6 through 11 years weighing ~66 pounds or more and people age 12 years and older

Please see [Important Safety Information](#) on pages 9-12 and [full Prescribing Information](#), including [Patient Information](#).

Every dose matters

 Together, the medicines that make up SYMDEKO target the underlying cause. Talk to your healthcare provider about all of the medicines you or your child takes, as the dose of SYMDEKO may need to be adjusted. Be sure to take every dose exactly as prescribed by your healthcare provider, because every dose matters.

If you or your child misses a dose

6 hours or less

from the time you or your child usually takes the morning or evening dose

Take the missed dose with fat-containing food as soon as possible. Then take the next dose at the usual time.

More than 6 hours

from the time you or your child usually takes the morning or evening dose

Do not take the missed dose. Take the next dose at the usual time with fat-containing food.

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

SYMDEKO and fat-containing foods

SYMDEKO should always be taken with a fat-containing meal or snack to help the body absorb the medicine.

Be sure to avoid foods and drinks that contain grapefruit while taking SYMDEKO because they may affect the amount of SYMDEKO in the body.






Everyday **CF**

Get delicious recipes and food ideas on [Everyday-CF.com](https://www.Everyday-CF.com).

Please see Important Safety Information on pages 9-12 and full Prescribing Information, including Patient Information.


WHAT SHOULD I TELL MY DOCTOR BEFORE STARTING SYMDEKO?

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

-  have or have had liver problems
-  are allergic to SYMDEKO or any ingredients in SYMDEKO. See the Patient Information for a list of ingredients
-  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

Please see additional Important Safety Information on pages 10-12 and full Prescribing Information, including Patient Information.

ARE THERE ANY OTHER MEDICINES THAT MAY INTERACT WITH SYMDEKO?

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

SYMDEKO may affect the way other medicines work and other medicines may affect how SYMDEKO works. The dose of SYMDEKO 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 such as ketoconazole, itraconazole (such as SPORANOX®), posaconazole (such as NOXAFIL®), voriconazole (such as VFEND®), or fluconazole (such as DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (such as BIAXIN®), or erythromycin (such as ERY-TAB®)

WHAT SHOULD I AVOID WHILE TAKING SYMDEKO?



SYMDEKO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve




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

Please see additional Important Safety Information on pages 9, 11, and 12, and full Prescribing Information, including Patient Information.

Q 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
- loss of appetite
- yellowing of your skin or the white part of your eyes
- nausea or vomiting
- dark, amber-colored urine



Serious allergic reactions have happened to people who are treated with SYMDEKO. Call your doctor 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
- light-headedness or dizziness



Abnormality of the eye lens (cataract) has happened 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 to look for cataracts.



before
treatment with
SYMDEKO



during
treatment with
SYMDEKO

Please see additional Important Safety Information on pages 9, 10, and 12, and full Prescribing Information, including Patient Information.

Q WHAT WERE THE MOST COMMON SIDE EFFECTS SEEN IN CLINICAL STUDIES WITH SYMDEKO?

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

Tell your doctor if you have any side effect that bothers you or that does not go away.



The side effect information above is based on what was reported in 2 different studies of people age 12 years and older, where a total of 334 people took SYMDEKO and 343 people took placebo.

Q DID PEOPLE EXPERIENCE RESPIRATORY EVENTS (BREATHING PROBLEMS)?



Q DID PEOPLE STOP TREATMENT DUE TO SIDE EFFECTS?



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 SYMDEKO. Call your doctor for medical advice about side effects.

You may report side effects to FDA at 1-800-FDA-1088.

Please see additional Important Safety Information on pages 9-11 and full Prescribing Information, including Patient Information.

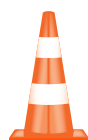
SYMDEKO® WAS STUDIED IN CHILDREN AGE 6 THROUGH 11 YEARS

Safety study details

In a safety study of 70 children with CF, the safety of SYMDEKO was evaluated. Participants were age 6 through 11 years with 2 copies of the F508del mutation or 1 copy of the F508del mutation and a second mutation in the CF gene predicted to respond to SYMDEKO. The primary purpose of this study was to determine the safety and tolerability of SYMDEKO.

- Each child took SYMDEKO every 12 hours with fat-containing food for 24 weeks (~6 months)
- Participants continued to take their other prescribed CF therapies
- All patients knew they were taking SYMDEKO, and no children in the study took placebo

SAFETY STUDY RESULTS



SAFETY through 24 weeks

The safety of SYMDEKO observed in the study was similar to what was observed in people age 12 years and older.



Please see pages 9-11 for Important Safety Information.

For Side Effects and Additional Safety Information in people age 12 years and older, please see page 12.

Please see Important Safety Information on pages 9-12 and full Prescribing Information, including Patient Information.

SAFETY STUDY CONSIDERATIONS

- Because no one took placebo in the safety study, it is not known if the changes in lung function and sweat chloride levels were due to SYMDEKO[®]
- A decrease in sweat chloride levels does not mean there will be an improvement in lung function (FEV₁)
- Keep in mind, all results shown are an average of all people studied and differed among individuals and mutations. Your child may have a different experience

ADDITIONAL SAFETY STUDY RESULTS



SWEAT CHLORIDE LEVELS

through 24 weeks

DECREASED BY

-14.5
mmol/L

Decreased sweat chloride levels by 14.5 mmol/L on average

Sweat chloride is a measure of the amount of salt in a person's sweat (mmol/L). People with CF have high levels of sweat chloride.



LUNG FUNCTION (FEV₁)*

through 24 weeks

+0.9 PERCENTAGE
POINT CHANGE

Lung function changed by 0.9 percentage points on average

Lung function is determined with an FEV₁ test, which measures how much air a person can exhale in a forced breath. Lung function was part of the safety assessment in this trial.

*FEV₁=percent predicted forced expiratory volume in 1 second.

Please see [Important Safety Information](#) on pages 9-12 and [full Prescribing Information](#), including [Patient Information](#).



STUDY DETAILS: PEOPLE AGE 12 YEARS AND OLDER WITH RESPONSIVE MUTATIONS (SHORT- AND LONG-TERM STUDIES)

People with the following mutations enrolled in the studies: 2789+5G→A, 3272-26A→G, 3849+10kbC→T, 711+3A→G, A455E, D110H, D1152H, D579G, E831X, L206W, P67L, R1070W, R117C, R347H, R352Q, S945L, and S977F. View all mutations that are responsive to SYMDEKO, including those that were studied only in a laboratory setting, at [SYMDEKO.com/eligibility](https://www.symdeko.com/eligibility).

SYMDEKO® WAS STUDIED FOR UP TO 2 YEARS

Short-term study

In a clinical study of 244 people with CF (Study 2), SYMDEKO was compared with ivacaftor and placebo to determine the possible benefits and risks of SYMDEKO. Participants were age 12 years and older with the F508del mutation and a second mutation in the CF gene predicted to respond to SYMDEKO.

- Each person had two 8-week treatment periods where they took either placebo, ivacaftor, or SYMDEKO every 12 hours with fat-containing food. Participants received 2 of the 3 possible treatments after completing both treatment periods
 - 161 patients took SYMDEKO, 156 patients took ivacaftor, and 161 patients took placebo
 - Between treatment periods there was an 8-week washout period where they did not take SYMDEKO, placebo, or ivacaftor
- Participants continued to take their other prescribed CF therapies

Keep in mind, results shown on the following pages are an average of all people studied and differed among individuals and mutations. You or your child may have a different experience.

Long-term study: 96 weeks (2 years)

After the short-term study (Study 2) ended, 226 people participated in the long-term study.

- The main focus of the study was to evaluate the safety of treatment with SYMDEKO
- Everyone took SYMDEKO every 12 hours with fat-containing food, and they continued to take their other prescribed CF therapies

Long-term study considerations

- The long-term study did not have any participants who took placebo. All patients knew they were taking SYMDEKO, which may have influenced the results
- The FDA did not consider the full long-term study when approving SYMDEKO, and it is not included in the full Prescribing Information. The long-term study may not meet the FDA's definition of an acceptable study because there was no placebo group included for comparison

Keep in mind, results shown on the following pages are an average of all people studied and differed among individuals and mutations. You or your child may have a different experience.

Please see Important Safety Information on pages 9-12 and full Prescribing Information, including Patient Information.

2 YEARS OF STUDY SUGGESTS THAT SYMDEKO® COULD HAVE A LONG-TERM IMPACT

People with the following mutations enrolled in the studies: 2789+5G→A, 3272-26A→G, 3849+10kbC→T, 711+3A→G, A455E, D110H, D1152H, D579G, E831X, L206W, P67L, R1070W, R117C, R347H, R352Q, S945L, and S977F. View all mutations that are responsive to SYMDEKO, including those that were studied only in a laboratory setting, at SYMDEKO.com/eligibility.

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SYMDEKO IMPROVED LUNG FUNCTION

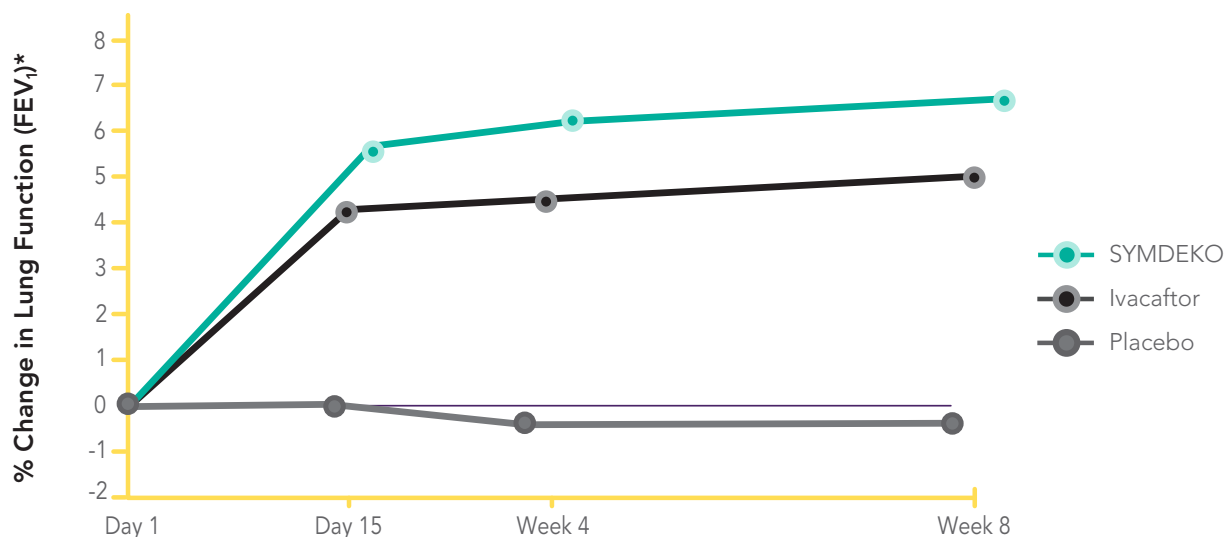


LUNG FUNCTION (FEV₁)*

average of Weeks 4 and 8

6.8 PERCENTAGE POINT
IMPROVEMENT VS PLACEBO
2.1 PERCENTAGE POINT
IMPROVEMENT VS IVACAFTOR

Improved lung function overall by an average of 6.8 percentage points compared with placebo. Additionally, improved lung function by an average of 2.1 percentage points compared with ivacaftor.



Changes in lung function varied by mutations (range -1.0 to 10.1 percentage points compared with placebo) and individuals.

LONG-TERM STUDY RESULTS from an additional 96 weeks (2 years)

Lung function improvements were generally maintained.

*FEV₁=percent predicted forced expiratory volume in 1 second.

No one in the long-term study took placebo for comparison. Therefore, it cannot be determined if the changes were due to SYMDEKO.

Please see [Important Safety Information](#) on pages 9-12 and [full Prescribing Information](#), including [Patient Information](#).

2 YEARS OF STUDY SUGGESTS THAT SYMDEKO® COULD HAVE A LONG-TERM IMPACT (CONTINUED)

People with the following mutations enrolled in the studies: 2789+5G→A, 3272-26A→G, 3849+10kbC→T, 711+3A→G, A455E, D110H, D1152H, D579G, E831X, L206W, P67L, R1070W, R117C, R347H, R352Q, S945L, and S977F. View all mutations that are responsive to SYMDEKO, including those that were studied only in a laboratory setting, at [SYMDEKO.com/eligibility](https://www.symdeko.com/eligibility).

Keep in mind, all results shown are an average of all people studied and differed among individuals and mutations. You or your child may have a different experience.

ADDITIONAL CLINICAL STUDY RESULTS



CF RESPIRATORY SYMPTOMS

average of Weeks 4 and 8

11.1 point overall improvement on average in CF respiratory symptoms compared with placebo

1.4 point change on average in CF respiratory symptoms compared with ivacaftor

- **It cannot be determined if this change was due to SYMDEKO**

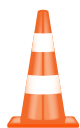
Changes in CF respiratory symptoms varied by mutations (range -11.1 to 29.2 percentage points compared with placebo).

LONG-TERM STUDY RESULTS from an additional 96 weeks (2 years)

CF respiratory symptom results were generally maintained.

A tool* was used to measure CF respiratory symptoms including cough, difficulty breathing, and amount of mucus coughed up.

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



SAFETY

The safety profile for people age 12 years and older, which includes serious and common side effects (see pages 11-12), was established through this short-term study as well as the short-term study on [page 18](#).

LONG-TERM STUDY RESULTS from an additional 96 weeks (2 years)

Safety was generally consistent with what was seen in the placebo-controlled clinical studies.

No one in the long-term study took placebo for comparison. Therefore, it cannot be determined if the changes were due to SYMDEKO.

Please see [Important Safety Information](#) on pages 9-12 and [full Prescribing Information](#), including [Patient Information](#).



STUDY DETAILS: PEOPLE AGE 12 YEARS AND OLDER WITH F508DEL/F508DEL (SHORT- AND LONG-TERM STUDIES)

SYMDEKO® WAS STUDIED FOR UP TO 2 YEARS

Short-term study

In a clinical study (Study 1) of 504 people with CF, SYMDEKO and placebo were compared to determine the possible benefits and risks of SYMDEKO. Participants were age 12 years and older with 2 copies of the F508del mutation in the CF gene.

- 248 people took SYMDEKO and 256 took placebo every 12 hours with fat-containing food for 24 weeks (~6 months)
- Participants continued to take their other prescribed CF therapies

Long-term study: 96 weeks (2 years)

After the short-term study ended, 459 people participated in the long-term study.

- The main focus of the study was to evaluate the safety of treatment with SYMDEKO
- Everyone took SYMDEKO every 12 hours with fat-containing food, and they continued to take their other prescribed CF therapies

Long-term study considerations

- The long-term study did not have any participants who took placebo. All patients knew they were taking SYMDEKO, which may have influenced the results
- The FDA did not consider the full long-term study when approving SYMDEKO, and it is not included in the full Prescribing Information. The full long-term study may not meet the FDA's definition of an acceptable study because there was no placebo group included for comparison

Keep in mind, all results shown on the following pages are an average of all people studied and differed among individuals. You or your child may have a different experience.

Please see Important Safety Information on pages 9-12 and full Prescribing Information, including Patient Information.

Keep in mind, all results shown are an average of all people studied and differed among individuals. You or your child may have a different experience.

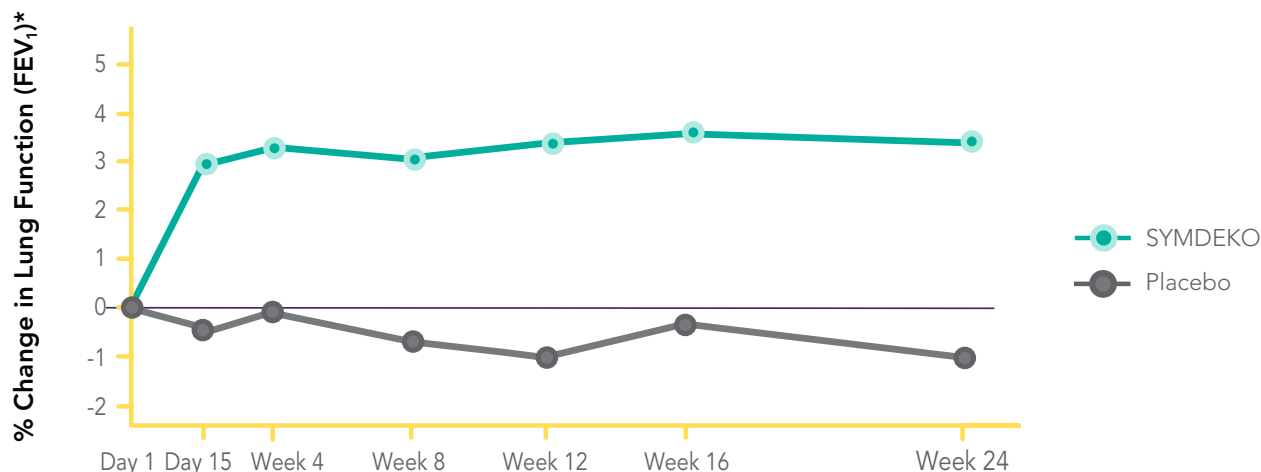
SYMDEKO IMPROVED LUNG FUNCTION



LUNG FUNCTION (FEV₁)* through 24 weeks

**4 PERCENTAGE POINT
IMPROVEMENT VS PLACEBO**

Improved lung function by 4 percentage points on average compared with those who took placebo.



*FEV₁=percent predicted forced expiratory volume in 1 second.



LONG-TERM STUDY RESULTS from an additional 96 weeks (2 years)

Lung function results were generally maintained above where they were before treatment.

No one in the long-term study took placebo for comparison. Therefore, it cannot be determined if the changes were due to SYMDEKO.

Please see Important Safety Information on pages 9-12 and full Prescribing Information, including Patient Information.

Keep in mind, all results shown are an average of all people studied and differed among individuals. You or your child may have a different experience.



PULMONARY EXACERBATIONS through 24 weeks

DECREASED BY
35%
VS PLACEBO

Lowered the risk of having a pulmonary exacerbation by **35%** on average compared with those who took placebo.

There were 78 pulmonary exacerbations in the SYMDEKO group and 122 in the placebo group.

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

LONG-TERM STUDY RESULTS from an additional 96 weeks (2 years)

A reduction in the number of pulmonary exacerbations per year was generally maintained over time.

ADDITIONAL CLINICAL STUDY RESULTS



BODY MASS INDEX (BMI) at 24 weeks

Increased by **0.06 kg/m²** on average compared with those who took placebo. BMI is a measure of someone's weight in relation to their height.

- For example, a person who is 5'4" and 110 pounds would gain 0.35 pounds, or a person who is 5'10" and 160 pounds would gain 0.42 pounds
- **It cannot be determined if this change was due to SYMDEKO**

LONG-TERM STUDY RESULTS from an additional 96 weeks (2 years)

BMI results were generally maintained.

No one in the long-term study took placebo for comparison. Therefore, it cannot be determined if the changes were due to SYMDEKO.

Please see Important Safety Information on pages 9-12 and full Prescribing Information, including Patient Information.

Keep in mind, all results shown are an average of all people studied and differed among individuals. You or your child may have a different experience.

ADDITIONAL CLINICAL STUDY RESULTS



CF RESPIRATORY SYMPTOMS through 24 weeks

5.1 point change on average in certain CF respiratory symptoms compared with those who took placebo

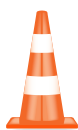
- **It cannot be determined if this change was due to SYMDEKO**

LONG-TERM STUDY RESULTS from an additional 96 weeks (2 years)

CF respiratory symptom results were generally maintained.

A tool* was used to measure CF respiratory symptoms including cough, difficulty breathing, and amount of mucus coughed up.

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



SAFETY

The safety profile for people age 12 years and older, which includes serious and common side effects (see pages 11-12), was established through this short-term study as well as the short-term study on [page 15](#).

LONG-TERM STUDY RESULTS from an additional 96 weeks (2 years)

Safety was generally consistent with what was seen in the placebo-controlled clinical studies.

No one in the long-term study took placebo for comparison. Therefore, it cannot be determined if the changes were due to SYMDEKO.

Please see [Important Safety Information](#) on pages 9-12 and [full Prescribing Information](#), including [Patient Information](#).

Q WHAT SHOULD I TELL MY DOCTOR BEFORE STARTING SYMDEKO?

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



have or have had liver problems



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



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

Q ARE THERE ANY OTHER MEDICINES THAT MAY INTERACT WITH SYMDEKO?



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

SYMDEKO may affect the way other medicines work and other medicines may affect how SYMDEKO works. The dose of SYMDEKO 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 such as ketoconazole, itraconazole (such as SPORANOX[®]), posaconazole (such as NOXAFIL[®]), voriconazole (such as VFEND[®]), or fluconazole (such as DIFLUCAN[®])
- antibiotics such as telithromycin, clarithromycin (such as BIAXIN[®]), or erythromycin (such as ERY-TAB[®])

Please see additional Important Safety Information on pages 9-12 and full Prescribing Information, including Patient Information.

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:




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
- loss of appetite
- yellowing of your skin or the white part of your eyes
- nausea or vomiting
- dark, amber-colored urine

 **Serious allergic reactions** have happened to people who are treated with SYMDEKO. Call your doctor 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
- light-headedness or dizziness

 **Abnormality of the eye lens (cataract)** has happened 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 to look for cataracts.



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

Please see additional Important Safety Information on pages 9-12 and full Prescribing Information, including Patient Information.



We're here to help you get there

Wherever life with cystic fibrosis (CF) takes you, Vertex GPS™: Guidance & Patient Support is here to help. We offer personalized, one-on-one support to help you start and stay on track with treatment. Once you're enrolled, you'll be assigned a dedicated Support Specialist who will be with you every step of the way.

Here are just some of the ways your Support Specialist can help:



Get you started on treatment by verifying your coverage and out-of-pocket costs with your **insurance company**. They'll also connect with your **healthcare provider** to discuss any requirements or questions your insurance company may have while determining coverage.



Help you explore financial assistance options, regardless of your insurance coverage. And if you have commercial insurance, the Vertex GPS Co-pay Assistance Program may be able to lower your co-pay to as little as \$0 per fill.*

*Eligibility restrictions and limitations apply. Annual assistance is limited to a maximum of \$20,000.



Keep you on track with your treatment by coordinating shipments with your **specialty pharmacy** and reminding you when it's time to refill your Vertex medicine. And if your daily routine changes, they can help you pre-plan refills, ship your medicine to a new address, and share tips to help you stay motivated.



Meet your everyday needs with information on nutrition and tips for staying physically active and maintaining a healthy mindset. And if you're caring for someone with CF, they'll send educational resources to help you teach your loved one about the importance of their daily treatment routine.



Plan for what's ahead as you approach big life changes. They can help you prepare for your next chapter and give you tips on staying on track with treatment. They can also share advice from others living with CF.



Not enrolled in Vertex GPS?

If you have been prescribed a Vertex medicine, ask your healthcare provider to complete an enrollment form for you.



Already enrolled?

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

Discover more about GPS and the support resources available at VertexGPS.com.



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