

## PATIENT INFORMATION

### **SYMDEKO (SIM-deh-koh)**

(tezacaftor/ivacaftor tablets; ivacaftor tablets) for oral use

#### **What is SYMDEKO?**

- SYMDEKO is a prescription medicine used for the treatment of cystic fibrosis (CF) in patients aged 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.

#### **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 end of this patient information leaflet for a complete list of ingredients in SYMDEKO.
- 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.

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

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

#### **How should I take SYMDEKO?**

- Take SYMDEKO exactly as your doctor tells you to take it.
- Take SYMDEKO by mouth only.
- **Always take SYMDEKO with food that contains fat.** Examples of fat-containing foods include eggs, butter, peanut butter, cheese pizza, and whole-milk dairy products such as whole milk, cheese, and yogurt.
- SYMDEKO consists of 2 different tablets.
- SYMDEKO Tablets (age 6 to less than 12 years weighing less than 30 kg):
  - The white tablet is marked with 'V50' and contains the medicines tezacaftor and ivacaftor. Take 1 white tablet 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.
- SYMDEKO Tablets (age 6 to less than 12 years weighing 30 kg or more and age 12 years and older):
  - The yellow tablet is marked with 'V100' and contains the medicines tezacaftor and ivacaftor. Take 1 yellow tablet 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 the morning and the evening tablet about **12** hours apart.

- If you miss a dose of SYMDEKO and:
  - it is **6 hours or less** from the time you usually take the yellow tablet in the morning or the light blue tablet in the evening, **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 yellow tablet in the morning or the light blue tablet in the evening, **do not take the missed dose**. Take your next dose at the usual time with food that contains fat.
- Do not take more than your recommended dose of SYMDEKO to make up for a missed dose.

**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.

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

- **Serious Allergic Reactions** can happen 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
- light-headedness or dizziness
- tightness of the chest or throat or difficulty breathing

- **Abnormality of the eye lens (cataract)** in some children and adolescents treated with SYMDEKO or treated 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
- sinus congestion
- nausea
- dizziness

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. 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.

**How should I store SYMDEKO?**

- Store SYMDEKO at room temperature between 68°F to 77°F (20°C to 25°C).

**Keep SYMDEKO and all medicines out of the reach of children.**

**General information about the safe and effective use of SYMDEKO.**

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

You can ask your pharmacist or doctor for information about SYMDEKO that is written for health professionals.

**What are the ingredients in SYMDEKO?**

**Tezacaftor/ivacaftor tablets:**

**Active ingredients:** tezacaftor and ivacaftor

**Inactive ingredients:** hypromellose acetate succinate, sodium lauryl sulfate, hypromellose, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, HPMC/hypromellose 2910, hydroxypropyl cellulose, titanium dioxide, talc, and iron oxide yellow (in tezacaftor 100 mg/ivacaftor 150 mg tablets only).

**Ivacaftor tablets:**

**Active ingredient:** ivacaftor

**Inactive ingredients:** colloidal silicon dioxide, croscarmellose sodium, hypromellose acetate succinate, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate, carnauba wax, FD&C Blue #2, PEG 3350, polyvinyl alcohol, talc, titanium dioxide, ammonium hydroxide, iron oxide black, propylene glycol, and shellac.



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For more information, go to [www.symdeko.com](http://www.symdeko.com) or call 1-877-752-5933.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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