SYMDEKO®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using SYMDEKO?

SYMDEKO contains the active ingredients tezacaftor and ivacaftor. SYMDEKO is used for the treatment of cystic fibrosis (CF) in patients aged 6 years and older who are homozygous for the *F508del* mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is listed in the approved indication.
For more information, see Section 1. Why am I using SYMDEKO? in the full CMI.

2. What should I know before I use SYMDEKO?

Do not use if you have ever had an allergic reaction to SYMDEKO or any of the ingredients listed at the end of the CMI.
Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are

breastfeeding. For more information, see Section 2. What should I know before I use SYMDEKO? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SYMDEKO and affect how it works.
A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use SYMDEKO?

Your doctor will tell you how much SYMDEKO you need to take each day. This may depend on your condition and whether or not you are taking other medicines.
SYMDEKO is for oral use.
More instructions can be found in Section 4. How do I use SYMDEKO? in the full CMI.

5. What should I know while using SYMDEKO?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using SYMDEKO. • Use SYMDEKO exactly as your doctor has prescribed.

	• Take SYMDEKO with fat-containing food and avoid food or drinks containing grapefruit or seville oranges. • Tell your doctor if you become pregnant while using SYMDEKO.
Things you should not do	• Do not stop using SYMDEKO or change the dose without first checking with your doctor. • Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.
Looking after your medicine	• Store below 30°C, in a dry place away from moisture, heat or sunlight. • Keep this medicine where young children cannot reach it.

For more information, see Section 5. What should I know while using SYMDEKO? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. Ask your doctor or pharmacist if you have any further questions about side effects. Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SYMDEKO.

Some common side effects experienced by patients taking SYMDEKO include the headache, throat and nose infections.

You may experience changes in mood or behaviour such as anxiety, depression, suicidal thoughts and behaviours, and trouble sleeping. If you experience significant pain or discomfort in the upper right stomach (abdominal) area, or yellowing of your skin or the white parts of your eyes these may be indicative of serious side effects associated with liver problems. If you experience rash, tightness of the chest or throat, difficulty breathing, or dizziness, these may be serious side effects associated with an allergic reaction. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

SYMDEKO (SIM-deh-koh)

Active ingredient(s): *Tezacaftor/Ivacaftor*, *Ivacaftor*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SYMDEKO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SYMDEKO.**

Where to find information in this leaflet:

1. Why am I using SYMDEKO?
2. What should I know before I use SYMDEKO?
3. What if I am taking other medicines?
4. How do I use SYMDEKO?
5. What should I know while using SYMDEKO?
6. Are there any side effects?
7. Product details

1. Why am I using SYMDEKO?

SYMDEKO contains the active ingredients Tezacaftor, Ivacaftor.

SYMDEKO is used for the treatment of cystic fibrosis (CF) in patients aged 6 years and older who are homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis

transmembrane conductance regulator (CFTR) gene that is listed in the approved indication.

SYMDEKO belongs to a group of medicines called “cystic fibrosis transmembrane conductance regulator (CFTR) modulators”. SYMDEKO includes two types of tablets, one contains tezacaftor and ivacaftor (morning dose) and the other contains ivacaftor (evening dose).

Tezacaftor is a “CFTR corrector” and works to increase the amount of protein at the cell surface.

Ivacaftor is a “CFTR potentiator” that makes the protein work better once it reaches the cell surface.

SYMDEKO is not addictive.

What is cystic fibrosis?

Cystic fibrosis is caused by genetic defects that limit the flow of chloride and water through cell membranes. As a result, the mucus in the lungs (and other organs) becomes thick and sticky, clogging the lungs and making it easier for germs to grow. SYMDEKO is a medicine that works by improving the flow of chloride and water in patients with cystic fibrosis who have a certain genetic defect.

2. What should I know before I use SYMDEKO?

Warnings

Do not use SYMDEKO if:

- you are allergic to tezacaftor, ivacaftor, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition (See Section 3. What if I am taking other medicines?)

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Tezacaftor and ivacaftor have been detected in breast milk. If you plan to breastfeed, ask your doctor for advice before taking SYMDEKO.

Use in children

Do not give SYMDEKO to children under 6 years of age.

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

Tell your doctor if you:

- have kidney disease or kidney problems in the past.
- have liver disease or you have had liver problems in the past.
- have received an organ transplant.
- you experience low mood or any other changes in mood and behaviour (such as anxiety, low or altered mood, suicidal thoughts or behaviours, or problems with sleep).

Laboratory Testing

Your doctor will do some blood tests to check your liver prior to and while you are taking SYMDEKO, particularly during the first year and especially if you have had high liver enzymes in the past. Increased liver enzymes in the blood have been seen in some people receiving SYMDEKO.

Your doctor may need to adjust your dose of SYMDEKO or monitor your blood tests for liver enzymes.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by SYMDEKO or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Take SYMDEKO with fat-containing food and avoid food or drinks containing grapefruit or Seville oranges.

Tell your doctor or pharmacist if you are taking any of the following:

Antifungal medicines *used for the treatment of fungal infections*	**ketoconazole, itraconazole, posaconazole, voriconazole, fluconazole**
Antibiotic medicines *used for treatment of bacterial infections*	telithromycin, clarithromycin, erythromycin, rifampicin, rifabutin, ciprofloxacin

Antifungal medicines *used for the treatment of fungal infections*	**ketoconazole, itraconazole, posaconazole, voriconazole, fluconazole**
Anticonvulsant medicines *used for the treatment of epileptic seizures*	phenobarbital, carbamazepine, phenytoin
Herbal medicine	St. John's wort (*Hypericum perforatum*)
Benzodiazepines *used for the treatment of anxiety, insomnia, agitation, etc*	midazolam
Immunosuppressants *used after organ transplantation*	ciclosporin, everolimus, sirolimus, tacrolimus
Cardiac glycosides *used for the treatment of congestive heart failure and an abnormal heart rhythm*	digoxin
Anticoagulants *used to prevent blood clots from forming or growing larger in blood and blood vessels*	warfarin

Antifungal medicines *used for the treatment of fungal infections*	**ketoconazole, itraconazole, posaconazole, voriconazole, fluconazole**
Medicines for diabetes	glimepiride, glipizide
Medicines for lowering blood cholesterol	pitavastatin

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking SYMDEKO.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SYMDEKO.

4. How do I use SYMDEKO?

How much to take

Your doctor will tell you how much SYMDEKO you need to take each day. This may depend on your condition and whether or not you are taking other medicines.

SYMDEKO dosing recommendations are as follows:

Patients aged 6 to <12 years weighing <30 kg

Morning dose:

One white tablet tezacaftor 50 mg/ivacaftor 75 mg

Evening dose:

One light blue tablet ivacaftor 75 mg

Patients aged 6 to <12 years weighing ≥ 30 kg

Morning dose:

One yellow tablet tezacaftor 100 mg/ivacaftor 150 mg

Evening dose:

One light blue tablet ivacaftor 150 mg

Patients aged ≥ 12 years

Morning dose:

One yellow tablet tezacaftor 100 mg/ivacaftor 150 mg

Evening dose:

One light blue tablet ivacaftor 150 mg

If you have liver problems, your doctor may need to reduce the dose as your liver is not clearing ivacaftor and tezacaftor as fast as in people who do not have liver problems. Follow all instructions given by your doctor, or health care professional.

When to take SYMDEKO

- SYMDEKO should be used every day and continue taking it for as long as your doctor tells you.
- Your doctor will determine if your treatment should be stopped.

How to take SYMDEKO

SYMDEKO is for oral use.

Do not break, chew or dissolve the tablets. Swallow the tablets whole.

Tablets

- Take 1 white (tezacaftor 50 mg/ ivacaftor 75 mg) or yellow tablet (tezacaftor 100mg/ivacaftor 150mg) in the morning with a fat-containing meal or snack. Avoid food containing grapefruit or Seville oranges.
- Take 1 light blue tablet (ivacaftor 75 mg or ivacaftor 150 mg) about 12 hours later in the evening with a fat containing meal or snack. Avoid food containing grapefruit or Seville oranges.

Examples of meals or snacks that contain fat are those prepared with butter or oils or those containing eggs.

Other fat-containing foods are:

- Cheese, whole milk, whole-milk dairy products, yoghurt, chocolate
- Meats, oily fish
- Avocados, hummus, soy-based products (tofu)
- Nuts, fat-containing nutritional bars or drinks

If you forget to use SYMDEKO

SYMDEKO should be used regularly at the same time each day.

Take the missed dose if less than 6 hours have passed since the time you missed the dose. Otherwise, wait until your next scheduled dose as you normally would.

Do not take a double dose to make up for the dose you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, talk to your doctor or pharmacist.

If you take too much SYMDEKO

If you think that you have used too much SYMDEKO, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using SYMDEKO?

Things you should do

Keep all of your doctor's appointments so that your progress can be checked.

- Use SYMDEKO exactly as your doctor has prescribed.
- Take SYMDEKO with fat-containing food and avoid food or drinks containing grapefruit.
- Tell your doctor if you become pregnant while using SYMDEKO.
- Tell your doctor if, for any reason, you have not used SYMDEKO exactly as prescribed.
- Your doctor may perform some eye examinations prior to and during treatment with SYMDEKO. Abnormality of the eye lens (cataract) without any effect on vision has been noted in some patients receiving this treatment.

Remind any doctor, dentist or pharmacist you visit that you are using SYMDEKO.

Things you should not do

- Do not stop using SYMDEKO or change the dose without first checking with your doctor.
- Do not let yourself run out of medicine over the weekend or on holidays.

- Do not give SYMDEKO to anyone else even if they have the same condition as you.
- Do not use SYMDEKO to treat other complaints unless your doctor tells you to.
- Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

Things to be careful of

Avoid food or drinks containing grapefruit or Seville oranges during treatment with SYMDEKO as this may increase the amount of SYMDEKO in your body.

SYMDEKO contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

Driving or using machines

SYMDEKO can make you dizzy. Do not drive or use machines unless you are sure that you are not affected.

If your child is taking SYMDEKO it is advised that he/she does not ride his/her bike or do anything else that needs his/her full attention unless you are sure that your child is not affected.

Looking after your medicine

- Store below 30°C. Store in original container.
- **Keep this medicine where young children cannot reach it.**

Do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Follow the instructions in the carton on how to take care of your medicine properly.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SYMDEKO.

Less serious side effects

Less serious side effects	What to do
Very common side effects (may affect more than 1 in 10 people) • Headache • Throat and nose infections Common side effects (may affect up to 1 in 10 people) • Feeling sick (nausea) • Sinus congestion • Dizziness	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
The following may be indicative of serious side effects associated with your liver. You may need urgent medical attention if you experience: • significant pain or discomfort in the	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
upper right stomach (abdominal) area. • yellowing of your skin or the white parts of your eyes. **The following may be indicative of serious side effects associated with an allergic reaction. You may need urgent medical attention if you experience:** • rash or hives. • tightness of the chest or throat, or difficulty breathing. • light-headedness or dizziness. **The following may be indicative of side effects associated with mood disturbances. Tell your doctor if you experience:** • depression. • suicidal thoughts. • anxiety.	

Serious side effects	What to do
• sleep disturbance.	

Serious side effects are uncommon.

This is not a complete list of all possible side effects. Your doctor or pharmacist has a more complete list.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell, even if it is not on this list.

Other side effects not listed here may occur in some people and there may be some side effects not yet known.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What SYMDEKO contains

Morning dose (SYMDEKO 50 mg/75 mg or SYMDEKO 100 mg/150 mg)

Active ingredient **(main ingredient)**	Tezacaftor, Ivacaftor
Other ingredients **(inactive ingredients)**	Hypromellose acetate succinate Sodium lauryl sulfate Hypromellose Microcrystalline cellulose Croscarmellose sodium Magnesium stearate *Film coating:* 50/75 mg tablets: Opadry complete film coating system 20A180008 White (PI No. 139612) 100/150 mg tablets: Opadry complete film coating system 20A120010 Yellow (PI No. 111630)

Evening dose (ivacaftor 75 mg or 150 mg)

Active ingredient **(main ingredient)**	Ivacaftor
Other ingredients **(inactive ingredients)**	Microcrystalline cellulose Lactose monohydrate Hypromellose acetate succinate Croscarmellose sodium Sodium lauryl sulfate Silicon dioxide Magnesium stearate Carnauba wax *Film coating:* OPACODE monogramming ink S-1-17823 BLACK (PI No. 12108) 75 mg: Opadry II complete film coating system 85F105098 Blue (PI No. 140157) 150 mg: Opadry II complete film coating system 85F90614 Blue (PI No. 108371)

Potential allergens	Lactose monohydrate

Do not take this medicine if you are allergic to any of these ingredients.

What SYMDEKO looks like

SYMDEKO 50 mg/75 mg and ivacaftor 75 mg

Morning dose

White, capsule-shaped tablet debossed with “V50” on one side and plain on the other (12.7 mm x 6.78 mm).

Evening dose

Light blue, capsule-shaped tablet, printed with “V 75” in black ink on one side and plain on the other (12.70 mm x 6.87 mm).

SYMDEKO 100 mg/150 mg and ivacaftor 150 mg

Morning dose

Yellow, capsule-shaped tablet debossed with “V100” on one side and plain on the other

(15.9 mm x 8.5 mm).

Evening dose

Light blue, capsule-shaped tablet, printed with “V150” in black ink on one side and plain on the other (16.5 mm x 8.4 mm).

SYMDEKO 50 mg/75 mg is Aust R 337367.

SYMDEKO 100 mg/150 mg is Aust R 298329.

Availability

SYMDEKO tablets are available in the following pack size:

- blister pack containing 56 film-coated tablets (28 tablets containing both tezacaftor and ivacaftor (morning dose) and 28 tablets containing ivacaftor (evening dose)).

SYMDEKO tablets are available in the following strength:

- SYMDEKO 50 mg/75 mg: tezacaftor 50 mg/ ivacaftor 75 mg and;

  ivacaftor 75 mg

- SYMDEKO 100 mg/150 mg: tezacaftor 100 mg/ ivacaftor 150 mg and;

  ivacaftor 150 mg

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Who distributes SYMDEKO

Vertex Pharmaceuticals (Australia) Pty Ltd

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