KALYDECO®

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 KALYDECO?

KALYDECO contains the active ingredient ivacaftor. KALYDECO is used for the treatment of cystic fibrosis (CF) in patients aged 1 month and older who have at least one mutation in the *CFTR* gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data.

For more information, see Section 1. Why am I using KALYDECO? in the full CMI.

2. What should I know before I use KALYDECO?

Do not use if you have ever had an allergic reaction to KALYDECO 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 KALYDECO? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with KALYDECO 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 KALYDECO?

Your doctor will tell you how much KALYDECO you need to take each day. This may depend on your condition and whether or not you are taking any other medicines. KALYDECO is for oral use.

More instructions can be found in Section 4. How do I use KALYDECO? in the full CMI.

5. What should I know while using KALYDECO?

Things you should do	• Remind any doctor, dentist or pharmacist

	you visit that you are using KALYDECO. • Use KALYDECO exactly as your doctor has prescribed. • Take KALYDECO with fat-containing food and avoid food containing grapefruit. • Tell your doctor if you become pregnant while using KALYDECO.
Things you should not do	• Do not stop using KALYDECO 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 KALYDECO? 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 KALYDECO.

Some common side effects experienced by patients taking KALYDECO include the common cold, sore throat and nasal congestion, headache, abdominal pain, diarrhoea and rash.

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 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.

KALYDECO® (kuh-LYE-deh-koh)

Active ingredient(s): *Ivacaftor*

Consumer Medicine Information (CMI)

This leaflet provides important information about using KALYDECO. **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 KALYDECO**

Where to find information in this leaflet:

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

1. Why am I using KALYDECO?

KALYDECO contains the active ingredient ivacaftor.

KALYDECO is used for the chronic treatment of cystic fibrosis (CF) in patients aged 1 month and older who have at least one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data.

KALYDECO belongs to a group of medicines called "cystic fibrosis transmembrane conductance regulator (*CFTR*) modulators."

In people with a *G551D* or other gating (class III) mutation and in people with an *R117H* mutation, the *CFTR* protein is present in normal amounts but its ability to allow chloride to pass through is reduced. KALYDECO is a *CFTR* potentiator, which is a drug that increases the opening of the *CFTR* protein, allowing more chloride to pass through.

KALYDECO 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, clogs the lungs and makes it easier for germs to grow. KALYDECO 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 KALYDECO?

Warnings

Do not use KALYDECO if:

- you are allergic to 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
- you take any medicines for any other condition (See Section 3. What if I am taking other medicines?)
- 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)
- your child displays behaviours that are different to their usual patterns whilst taking KALYDECO.

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.

Your doctor will help you decide what is best for you or your child.

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

It is unknown whether KALYDECO is excreted in human milk. If you plan to breast-feed, ask your doctor for advice before taking KALYDECO.

Use in children

Do not give KALYDECO to children weighing less than 3 kg or under 1 month of age.

The safety and efficacy of this medicine in children aged less than 1 months have not been established.

Abnormality of the eye lens (cataract) without any effect on vision has been noted in some children receiving KALYDECO.

Your doctor may perform some eye examinations prior to and during the treatment with KALYDECO.

Laboratory Testing

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

Talk to your doctor if you have been told you have liver or kidney disease or if you are taking any other medicine, as your doctor may need to adjust the dose of KALYDECO.

Increased liver enzymes in the blood have been seen in some people receiving KALYDECO. Tell your doctor right away if you have any of these symptoms, which may be a sign of liver problems:

- pain or discomfort in the upper right abdominal area
- yellowing of the skin or the white part of the eyes
- loss of appetite

- nausea or vomiting
- dark urine

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 interfere with KALYDECO and affect how it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Take KALYDECO with fat-containing food and avoid food containing grapefruit.

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

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
Anti-inflammatory medicines *used for the treatment of inflammation*	dexamethasone, high-dose prednisone
Herbal medicine	St. John's wort (*Hypericum perforatum*)
Benzodiazepines *used for the treatment of anxiety, insomnia, agitation, etc.*	midazolam, alprazolam, diazepam, triazolam
Immunosuppressants *used after organ transplantation*	ciclosporin, tacrolimus
Cardiac glycosides *used for the treatment of mild to moderate congestive heart failure and an abnormal heart rhythm*	digoxin

Antifungal medicines *used for the treatment of fungal infections*	**ketoconazole, itraconazole, posaconazole, voriconazole, fluconazole**
Anticoagulants *used to prevent blood clots from forming or growing larger in blood and blood vessels*	warfarin

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

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

4. How do I use KALYDECO?

How much to take

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

KALYDECO dosing recommendations for patients aged 1 months and older are as follows:

Age	Weight	Dose	Total daily dose
1 mo to les tha 2 mo	>3 kg	On sac of 13. mg gra tak ora eve 24 hou	13.4 mg (one sachet) es
2 mo to les tha 4 mo	≥ 3 kg	On sac of 13. mg gra tak ora eve 12 hou	26.8 mg (two sachets) es
4 mo to les	≥ 5 kg	On sac of 25	50 mg (two sachets)

Age	Weight	Dose	Total daily dose
tha 6 mo		mg gra tak ora eve 12 hou	es
6 months and older	≥ 5 kg to <7 kg	On sac of 25 mg gra tak ora eve 12 hou	50 mg (two sachets) es
	≥ 7 kg to <14 kg	On sac of 50 mg gra tak ora eve	100 mg (two sachets) es

Age	Weight	Dose	Total daily dose
		12 hou	
	≥ 1 kg to <25 kg	On sac of 75 mg gra tak ora eve 12 hou	150 mg (two sachets) es
	≥ 2 kg	On 150 mg tab tak ora eve 12 hou	300 mg (two tablets)

If you have liver problems, your doctor may need to reduce the dose as your liver is not clearing ivacaftor as fast as in people who do not have problems with liver function.

When to take KALYDECO

- KALYDECO should be taken once daily in patients 1 month to less than 2 months old.
- KALYDECO should be taken twice daily (every 12 hours) for patients over 2 months old.

How to take KALYDECO

KALYDECO is for oral use.

Tablets

Take 1 tablet (150 mg) of KALYDECO every 12 hours by mouth with a fat-containing meal or snack.

Granules

KALYDECO should be taken by mouth with a fat-containing meal or snack. Each sachet is for single use only.

Giving KALYDECO to your child

- Hold sachet of granules with cut line on top.
- Shake sachet gently to settle contents.
- Tear or cut sachet open along cut line.
- Mix the entire content of a sachet with one teaspoon (5 mL) of age-appropriate soft food or liquid. Food or liquid should be at room temperature or below. Some

examples of age-appropriate soft foods or liquids include puréed fruits or vegetables, yogurt, water, breast milk, infant formula, whole milk, or juice.

- Once mixed, give the product to your child immediately. If this is not possible, give it within one hour after mixing. Ensure that the mixture is completely and immediately consumed.
- A fat-containing meal or snack should be given to your child just before or just after dosing.

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

If you forget to take KALYDECO

KALYDECO should be used regularly at the same time each day. If you miss your dose at the usual time, 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 KALYDECO

If you think that you have used too much KALYDECO, 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 KALYDECO?

Things you should do

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

- Use KALYDECO exactly as your doctor has prescribed.
- Take KALYDECO with fat-containing food and avoid food containing grapefruit.
- Tell all doctors, dentists and pharmacists who are treating you that you are using KALYDECO.

- Tell your doctor if you become pregnant while using KALYDECO.
- Tell your doctor if, for any reason, you have not used KALYDECO exactly prescribed.

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

Things you should not do

- Do not stop using KALYDECO 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 KALYDECO to anyone else even if they have the same condition as you.
- Do not use KALYDECO 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 containing grapefruit during treatment with KALYDECO as they may increase the amount of KALYDECO in your body.
- KALYDECO tablets contains lactose. KALYDECO granules contains lactose, mannitol and sucralose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how KALYDECO affects you.

KALYDECO may cause dizziness in some people. Do not drive or use machines unless you are sure that you are not affected.

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

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.**

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.

Granules

Once mixed with food, KALYDECO granules are stable for one hour.

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 KALYDECO.

Less serious side effects

Less serious side effects	**What to do**
Very common side effects (may affect more than 1 in 10 people) • upper respiratory tract infection (the common cold), including sore throat and nasal congestion	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• headache • abdominal pain • diarrhoea • rash Common side effects (may affect up to 1 in 10 people) • sinus congestion • red throat • runny nose • dizziness • changes in the type of bacteria in mucus • ear pain, ear discomfort • ringing in the ears • redness inside the ear Uncommon side effects (may affect up to 1 in 100 people) • ear congestion • breast inflammation • breast mass • enlargement of the breast • nipple changes or pain	

Serious side effects

Serious side effects	What to do
• Significant pain or discomfort in the upper right abdominal area. • Yellowing of your skin or the white parts of your eyes. • Rash or hives. • Tightness of the chest or throat or difficulty breathing. • Light-headedness or dizziness. • Depression. • Suicidal thoughts. • Anxiety. • Sleep disturbances. • Behavioural changes in young children (2-5 yrs).	**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.**

These may be indicative of serious side effects. You may need urgent medical attention. Serious side effects are uncommon.

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

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

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, Opadry II complete film coating system 85F90614 Blue (PI# 108371), OPACODE monogramming ink S-1-17823 BLACK (PI# 12108).
Potential allergens	Lactose monohydrate

What KALYDECO granules contain

Active ingredient (main ingredient)	ivacaftor
Other ingredients (inactive ingredients)	silicon dioxide, croscarmellose sodium, hypromellose acetate succinate, lactose monohydrate, magnesium stearate, mannitol, sucralose, sodium lauryl sulfate.

Potential allergens	Lactose monohydrate, mannitol and sucralose

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

What KALYDECO looks like

KALYDECO 150 mg film-coated tablets are light blue, capsule-shaped tablets, 16.5 mm x 8.4 mm, printed with "V 150" in black ink on one side and plain on the other. (150 mg blister pack: Aust R 198655).

KALYDECO 13.4mg, 25 mg, 50 mg and 75 mg granules are white to off-white sweetened, unflavoured granules approximately 2 mm in diameter.

(13.4 mg sachet: Aust R 449865; 25 mg sachet: Aust R 342815; 50 mg sachet: Aust R 267390; 75 mg sachet: Aust R 269661)

Availability

Tablets

- KALYDECO 150 mg tablets are available in in a blister pack containing 56 film-coated tablets.

Granules

- KALYDECO 25 mg, 50 mg and 75 mg granules are available in the following pack size:
  - 56 sachets (containing 4 individual wallets with 14 sachets per wallet)

- KALYDECO 13.4 mg is available in the following pack sizes:
  - 56 sachets (containing 4 individual wallets with 14 sachets per wallet)
  - 28 sachets (containing 4 individual wallets with 7 sachets per wallet)

Who distributes KALYDECO

Vertex Pharmaceuticals (Australia) Pty Ltd

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Australia

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