

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the more common questions about KALYDECO tablets and granules.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking KALYDECO against the benefits he/she expects it will have for you.

If you have any concerns or questions about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What KALYDECO is used for

KALYDECO is for the chronic treatment of cystic fibrosis (CF) in patients aged 2 years and older who have a G551D or other gating (class III) mutation in the CFTR gene.

KALYDECO is for the chronic treatment of cystic fibrosis (CF) in patients aged 6 years and older who have an R117H mutation in the CFTR gene.

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.

How KALYDECO works

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.

Before you take KALYDECO

When you must not take it

Do not take KALYDECO if you have an allergy to:

- any medicine containing ivacaftor, the active ingredient in KALYDECO.
- any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If the medicine has expired or the packaging is damaged, return it to your pharmacist for disposal.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

If you are pregnant or plan to become pregnant, ask your doctor for advice before taking this medicine.

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

If you are breast-feeding or plan to breast-feed, ask your doctor for advice before taking this medicine.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may be affected by KALYDECO 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 KALYDECO with fat-containing food and avoid food 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 the treatment of bacterial infections):** telithromycin, clarithromycin, erythromycin, rifampicin, rifabutin
- Anticonvulsant medicines (used for the treatment of epileptic seizures):** phenobarbital, carbamazepine, phenytoin
- Herbal medicines:** St. John's wort (*Hypericum perforatum*)
- Benzodiazepines (used for the treatment of anxiety, insomnia, agitation, etc.):** midazolam, alprazolam, diazepam, triazolam
- Immunosuppressants (used after an organ transplantation):** cyclosporine, tacrolimus
- Cardiac glycosides (used for the treatment of mild to moderate congestive heart failure and an abnormal heart rhythm called atrial fibrillation):** digoxin
- 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.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

Use in children

Do not give KALYDECO to children weighing less than 10 kg or under 2 years of age.

The safety and effectiveness of this medicine in children aged 2 to less than 6 years beyond 24 weeks and less than 2 years of age have not been studied.

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 stomach (abdominal) area
- yellowing of the skin or the white part of the eyes
- loss of appetite
- nausea or vomiting
- dark urine

How to take KALYDECO

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

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 2 years and older are as follows:

- Patients weighing less than 14 kg:** one sachet of 50 mg granules taken orally every 12 hours (total daily dose of 100 mg)
- Patients weighing 14 kg to less than 25 kg:** one sachet of 75 mg granules taken orally every 12 hours (total daily dose of 150 mg)
- Patients weighing 25 kg or more:** one 150 mg tablet taken orally every 12 hours (total daily dose of 300 mg)

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.

How to take it

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

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

How long to take it

Take KALYDECO every day and continue taking it for as long as your doctor tells you.

Your doctor will determine if your treatment should be stopped.

If you forget to take it

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 that 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 (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26) for advice, or go to the Emergency Department at the nearest hospital, if you think that you or anyone else may have taken too much KALYDECO. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking KALYDECO

Things you must do

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

Use KALYDECO exactly how your doctor has prescribed.

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

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 as prescribed.

Things you must 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 or Seville oranges during treatment with KALYDECO as they may increase the amount of KALYDECO in your body.

Be careful driving or operating machinery until you know how KALYDECO affects you.

KALYDECO can make you dizzy. 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 needs his/her full attention unless you are sure that your child is not affected.

KALYDECO contains lactose.

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

Side effects

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

All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if...

Tell your doctor or pharmacist if you notice any of the following and they worry you:

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

- headache
- abdominal pain
- diarrhoea
- rash

Common side effects (may affect up to 1 in 10 people)

- sinus congestion
- 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

Go to hospital if...

Tell your doctor immediately or go to the Emergency Department at your nearest hospital if you notice any of the following:

- significant pain or discomfort in the upper right stomach (abdominal) area
- yellowing of your skin or the white part of your eyes

These may be indicative of serious side effects. You may need urgent medical attention. 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. Others may occur in some people and there may be some side effects not yet known.

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

Other side effects not listed above may also occur in some people.

After taking KALYDECO

Storage

Store below 30°C. Keep this medicine out of the sight and reach of children.

Granules

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

Disposal

If your doctor tells you to stop using KALYDECO or KALYDECO has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

Availability

Tablets

KALYDECO tablets are available in the following pack sizes:

- blister pack containing 56 film-coated tablets
- child-resistant bottle containing 56 film-coated tablets

KALYDECO tablets are available in the following strength:

- 150 mg

Granules

KALYDECO granules are available in the following pack sizes:

- 56 sachets (containing 4 individual wallets with 14 sachets per wallet)

KALYDECO granules are available in the following strengths:

- 50 mg
- 75 mg

What does KALYDECO look like

Tablets

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.

Granules

White to off-white sweetened, unflavoured granules approximately 2 mm in diameter.

Ingredients

Active ingredient

- ivacaftor

Inactive ingredients

Tablets

- 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).

Granules

- silicon dioxide, croscarmellose sodium, hypromellose acetate succinate, lactose monohydrate, magnesium stearate, mannitol, sucralose, sodium lauryl sulfate.

Sponsor

Vertex Pharmaceuticals
(Australia) Pty Ltd
Suite 3, Level 3
601 Pacific Highway
St Leonards
NSW 2065
Australia

ARTG Numbers

150 mg film-coated tablets, blister pack
AUST R 198655

150 mg film-coated tablets, bottle AUST R
198654

50 mg granules, sachet AUST R 267390

75 mg granules, sachet AUST R 269661

This leaflet was prepared 16 September 2016

©2016 Vertex Pharmaceuticals Incorporated

KALYDECO, VERTEX and the VERTEX triangle logo are registered trademarks of Vertex Pharmaceuticals Incorporated.