

## 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 taking ACETEC?

ACETEC contains the active ingredient enalapril maleate. ACETEC is used to lower high blood pressure, which doctors call hypertension. It is also used to treat heart failure.

For more information, see Section [1. Why am I taking ACETEC?](#) in the full CMI.

### 2. What should I know before I take ACETEC?

Do not use if you have ever had an allergic reaction to ACETEC 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 take ACETEC?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ACETEC 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 take ACETEC?

- Your doctor will tell you how many tablets you need to take each day.
- This depends on your condition and whether you are taking other medicines.

More instructions can be found in Section [4. How do I take ACETEC?](#) in the full CMI.

### 5. What should I know while taking ACETEC?

|                                    |   |
|------------------------------------|---|
| <b>Things you should do</b>        | <ul style="list-style-type: none"> <li>• Remind any doctor, dentist or pharmacist you visit that you are taking ACETEC.</li> <li>• Go to your doctor regularly for a check-up. Have your blood pressure checked when your doctor says, to make sure ACETEC is working.</li> <li>• If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up.</li> <li>• Make sure you drink enough water during exercise and hot weather when you are taking ACETEC, especially if you sweat a lot.</li> <li>• If you have excessive vomiting and/or diarrhoea while taking ACETEC, tell your doctor.</li> </ul> |
| <b>Things you should not do</b>    | <ul style="list-style-type: none"> <li>• Do not stop taking your medicine or lower the dosage without checking with your doctor.</li> <li>• Do not give ACETEC to anyone else, even if they have the same condition as you.</li> </ul>  |
| <b>Driving or using machines</b>   | <ul style="list-style-type: none"> <li>• ACETEC may cause dizziness or light-headedness in some people. Make sure you know how you react to ACETEC before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.</li> </ul>  |
| <b>Drinking alcohol</b>            | <ul style="list-style-type: none"> <li>• If you drink alcohol, dizziness or light-headedness may be worse.</li> </ul>   |
| <b>Looking after your medicine</b> | <ul style="list-style-type: none"> <li>• Keep your tablets in a cool dry place where the temperature stays below 25°C.</li> <li>• Keep your tablets in the blister pack until it is time to take them.</li> </ul>   |

For more information, see Section [5. What should I know while taking ACETEC?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects include headache, light-headedness or dizziness, fatigue, dry cough, mild stomach upsets and muscle cramps. Serious side effects include fast or irregular heartbeat, fainting, yellowing of the skin or eyes, skin rash, worrying or frequent infections, signs of dehydration or symptoms of an allergic reaction (i.e., swelling of the face or throat, hives, shortness of breath etc.).

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.

## Consumer Medicine Information (CMI)

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

**Where to find information in this leaflet:**

1. [Why am I taking ACETEC?](#)
2. [What should I know before I take ACETEC?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take ACETEC?](#)
5. [What should I know while taking ACETEC?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

### 1. Why am I taking ACETEC?

**ACETEC contains the active ingredient enalapril maleate.**

ACETEC belongs to a group of medicines called Angiotensin Converting Enzyme (ACE) inhibitors.

**ACETEC lowers high blood pressure, which doctors call hypertension. It is also used to treat heart failure.**

One of the ways ACETEC helps lower blood pressure and treat heart failure is that it widens blood vessels. This means that blood is able to pass through them more easily and the heart doesn't have to pump as hard to move blood around the body. This also means that when you place extra demands on your heart, such as during exercise, the heart may cope better so you may not get short of breath as easily.

#### **Hypertension:**

Everyone has blood pressure. This pressure helps get your blood all around your body. Your blood pressure may be different at different times of the day, depending on how busy or worried you are. You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems. You may feel fine and have no symptoms, but eventually hypertension can cause stroke, heart disease and kidney failure. ACETEC helps to lower your blood pressure.

#### **Heart Failure:**

Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body. Heart failure is not the same as heart attack and does not mean that the heart stops working. Heart failure may start off with no symptoms, but as the condition progresses, patients may feel short of breath or may get tired easily after light physical activity

such as walking. Some patients may wake up short of breath at night. Fluid may collect in different parts of the body, often first noticed as swollen ankles and feet.

ACETEC helps to treat heart failure, whether you have symptoms or not. In many patients with heart failure who have symptoms, ACETEC may slow the progression of heart failure and reduce the need to go to hospital as a result of heart failure. ACETEC may help some of these patients live longer.

In many patients with heart failure who have no symptoms, ACETEC may help to stop the heart muscle from getting weaker. ACETEC may also slow down the development of symptoms, such as shortness of breath, tiredness after light physical activity, or swelling of the ankles and feet. These patients may be less likely to have hospital stays due to heart failure.

By taking ACETEC, heart failure patients may have less chance of having a heart attack.

When used to treat heart failure, ACETEC is almost always used with other medicines called diuretics or fluid tablets. These medicines help the kidney get rid of excess fluid from the body.

Your doctor may prescribe ACETEC for another reason. Ask your doctor if you have any questions about why ACETEC has been prescribed for you.

ACETEC is not addictive.

### 2. What should I know before I take ACETEC?

#### **Warnings**

#### **Do not take ACETEC if:**

- you are allergic to enalapril maleate, or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction to ACETEC may include:

- o skin rash, itchiness
- o shortness of breath
- o swelling of the face, lips or tongue
- o muscle pain or tenderness or joint pain.

Always check the ingredients to make sure you can use this medicine.

- you have taken any other 'ACE inhibitor' medicines for high blood pressure or heart failure before, which caused your face, lips, tongue, throat, hands, or feet to swell up, or made it hard for you to breathe.

If you have had an allergic reaction to an ACE inhibitor before, you may be allergic to ACETEC.

- you have a history of swelling of the face, lips, tongue, throat, hands, or feet, for no apparent reason.

- you have diabetes and are taking a medicine called aliskiren to reduce blood pressure.
- you are taking a medicine containing a neprilysin inhibitor (e.g., sacubitril). Do not take ACETEC for at least 36 hours before or after you take sacubitril/valsartan, a medicine containing a neprilysin inhibitor.
- you are pregnant or breast-feeding.
- the packaging is torn or shows signs of tampering.
- the expiry date on the pack has passed. If you take this medicine after the expiry date has passed, it may not work.

**If you are not sure whether you should start taking ACETEC, talk to your doctor.**

#### **Check with your doctor if you:**

- have any other medical conditions especially the following:
  - o kidney disease, or are undergoing dialysis.
  - o diabetes
  - o heart problems.
- have recently suffered from excessive vomiting or diarrhoea.
- are following a very low salt diet.
- are taking potassium supplements, potassium-sparing agents, potassium-containing salt substitutes or other drugs that may increase serum potassium (e.g., trimethoprim-containing products).
- have had an allergy to any other medicines or any other substances, such as foods, preservatives, or dyes.
- suffer from low blood pressure (you may notice this as faintness or dizziness, especially when standing).
- are scheduled for surgery and anaesthesia (even at the dentist office), as there may be a sudden fall in blood pressure associated with anaesthesia.
- are taking a medicine containing a neprilysin inhibitor (e.g., sacubitril).
- are taking a medicine containing vildagliptin.
- take any medicines for any other condition.

If you have not told your doctor about any of the above, tell them before you take any ACETEC.

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**

Tell your doctor if you are pregnant or intend to become pregnant.

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

**ACETEC should not be taken during pregnancy or while breast-feeding.**

Your baby may absorb this medicine in the womb or from breast milk and therefore there is a possibility of harm to the baby.

### **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 ACETEC and affect how it works.** You may need to take different amounts of your medicines, or you may need to take different medicines.

**Medicines that may increase the effect of ACETEC include:**

- other blood pressure medicines
- diuretic tablets - also called fluid or water tablets.
- potassium tablets
- potassium-containing salt substitutes
- potassium-sparing agents (e.g., spironolactone, eplerenone, triamterene, amiloride)
- other drugs that may increase serum potassium (e.g., trimethoprim-containing products)
- arthritis medicines including gold therapy
- mammalian target of rapamycin (mTOR) inhibitors (e.g., temsirolimus, sirolimus, everolimus) or a medicine containing a neprilysin inhibitor (e.g., sacubitril) or vildagliptin as coadministration with ACETEC could increase the risk for an allergic reaction called angioedema.

**Medicines that may reduce the effect of ACETEC include:**

- non-steroidal anti-inflammatory medicines (NSAIDs or Coxibs/COX-2 inhibitors), used to relieve pain, swelling and other symptoms of inflammation.

**Medicines that may be affected when taken with ACETEC include:**

- lithium, a medicine used to treat mood swings and some types of depression.
- insulin or oral antidiabetic medicines. You should be closely monitored for low blood glucose levels, especially during the first month of treatment with ACETEC.

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

### **4. How do I take ACETEC?**

#### **How much to take**

- Your doctor will tell you how many tablets you need to take each day.
- This depends on your condition and whether you are taking other medicines.
- Take ACETEC only when prescribed by your doctor.
- ACETEC helps control your high blood pressure and helps improve your heart failure but does not cure it. Therefore, ACETEC must be taken every day. Continue taking ACETEC for as long as your doctor prescribes.

**For high blood pressure:**

- For most patients, the usual starting dose is 5 mg taken once a day.
- Some patients may need a lower starting dose.
- The dose may need to be increased depending on your blood pressure.
- Most patients take between 10 to 40 mg each day.

#### **For heart failure:**

- The usual starting dose is 2.5 mg taken once a day.
- Depending on your response, this dose may need to be increased up to 20 mg each day.
- This dose may be taken once a day or divided into two doses per day.

#### **When to take ACETEC**

- ACETEC should be taken at about the same time each day. Taking your tablet(s) at the same time each day will have the best effect. It will also help you remember when to take the tablets.
- It does not matter if you take ACETEC before or after food.

#### **How to take ACETEC**

- Swallow ACETEC with a glass of water.

#### **If you forget to take ACETEC**

ACETEC should be taken regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking your tablet(s) as you would normally.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**If you are not sure whether to skip the dose, talk to your doctor or pharmacist.**

**Do not take a double dose to make up for the dose you missed.**

If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

#### **If you take too much ACETEC**

If you take too many tablets, you will probably feel light-headed or dizzy, or you may faint.

If you think that you or anyone else has taken too much ACETEC, urgent medical attention may be needed.

#### **You should immediately:**

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 taking ACETEC?**

### **Things you should do**

- Have your blood pressure checked when your doctor says, to make sure ACETEC is working.
- If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up. You may feel light-headed or dizzy, especially if you are also taking a diuretic (fluid tablet). This may be because your blood pressure is falling suddenly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem gets worse or continues, talk to your doctor.
- If you plan to have surgery (even at the dentist) that needs a general anaesthetic, tell your doctor or dentist that you are taking ACETEC. Your blood pressure may drop suddenly.
- Make sure you drink enough water during exercise and hot weather when you are taking ACETEC, especially if you sweat a lot. If you do not drink enough water while taking ACETEC, you may faint or feel light-headed or sick. This is because your blood pressure is dropping suddenly. If you continue to feel unwell, tell your doctor.
- If you have excessive vomiting and/or diarrhoea while taking ACETEC, tell your doctor. This can also mean that you are losing too much water and salt and may drop your blood pressure too much.
- Go to your doctor regularly for a check-up.
- Your doctor may occasionally do a blood test to check your potassium level in the blood and to see how your kidneys are working.
- If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking ACETEC.
- Remind any doctor, dentist or pharmacist you visit that you are using ACETEC.

### **Call your doctor straight away if you:**

- become pregnant while taking ACETEC.
- feel any light-headedness or dizziness after you take your first dose of ACETEC or if your dose is increased. This is especially important if you are taking ACETEC for heart failure.

### **Things you should not do**

- Do not give ACETEC to anyone else, even if they have the same condition as you.
- Do not take ACETEC to treat any other complaints unless your doctor tells you to.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.

### **Things that would be helpful for your blood pressure or heart failure**

Some self-help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- **Alcohol** - your doctor may advise you to limit your alcohol intake.
- **Diet** - eat a healthy diet which includes plenty of fresh vegetables, fruit, bread, cereals, and fish. Also eat less fat and sugar.
- **Exercise** - regular exercise helps to reduce blood pressure and helps the heart get fitter, but it is important not to overdo it. Walking is good exercise but try to find a route that is fairly flat. Before starting any exercise, ask your doctor about the best kind of programme for you.
- **Salt** - your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake, you should avoid using salt in cooking or at the table.
- **Smoking** - your doctor may advise you to stop smoking or at least cut down.
- **Weight** - your doctor may suggest losing some weight to help lower your blood pressure and help lessen the amount of work your heart has to do. Some people may need a dietician's help to lose weight.

### Driving or using machines

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

ACETEC may cause dizziness or light-headedness in some people, especially after the first dose or if the dose is increased. Make sure you know how you react to ACETEC before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

If you drink alcohol, dizziness or light-headedness may be worse.

### Looking after your medicine

- Store below 25°C.
- Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the blister pack and store them in another container they will not keep well, and they may become soft and crumbly.

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

Store it in a cool dry place away from moisture, heat, or sunlight; for example, do not store it:

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

Heat and dampness can destroy some medicines.

**Keep it where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above ground is a good place to store medicines.

### 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.

### Less serious side effects

| Less serious side effects   | What to do   |
|---|--|
| <b>Heart and circulation-related:</b> <ul style="list-style-type: none"> <li>• light-headedness or dizziness because blood pressure is too low.</li> </ul> <b>Respiratory-related:</b> <ul style="list-style-type: none"> <li>• dry cough</li> </ul> <b>Gastrointestinal-related:</b> <ul style="list-style-type: none"> <li>• mild stomach upsets such as feeling sick, diarrhoea, or stomach pains.</li> </ul> <b>Muscle/skeleton-related:</b> <ul style="list-style-type: none"> <li>• muscle cramps</li> </ul> <b>General conditions:</b> <ul style="list-style-type: none"> <li>• headache</li> <li>• fatigue</li> </ul> | <b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b> |

### Serious side effects

| Serious side effects  | What to do   |
|---|--|
| <b>Allergic reaction:</b> <ul style="list-style-type: none"> <li>• swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing.</li> <li>• swelling of the hands, feet, or ankles</li> </ul> <b>Skin-related:</b> <ul style="list-style-type: none"> <li>• pinkish, itchy swellings on the skin, also called hives or nettlerash</li> </ul> <b>Heart and circulation-related:</b> <ul style="list-style-type: none"> <li>• chest pain, angina</li> <li>• collapse, numbness or weakness of arms or legs</li> </ul> <b>Respiratory-related:</b> <ul style="list-style-type: none"> <li>• wheeziness due to tightness in the chest</li> </ul> | <b>Stop taking ACETEC, 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.</b><br><br><b>Serious side effects are rare.</b> |
| <b>Heart and circulation-related:</b> <ul style="list-style-type: none"> <li>• changes in the way your heart beats, for example, if you notice it beating faster.</li> </ul>  | <b>Tell your doctor immediately if you notice any of these serious side effects.</b>   |

| Serious side effects  | What to do |
|---|------------|
| <ul style="list-style-type: none"> <li>fainting</li> </ul> <p><b>Gastrointestinal-related:</b></p> <ul style="list-style-type: none"> <li>yellowing of the skin and eyes, also called jaundice.</li> <li>fainting</li> </ul> <p><b>Skin-related:</b></p> <ul style="list-style-type: none"> <li>itchy skin rash or other skin problems</li> <li>signs of worrying or frequent infections such as fever, severe chills, sore throat, or mouth ulcers</li> </ul> <p><b>Kidney-related:</b></p> <ul style="list-style-type: none"> <li>passing less urine than is normal for you.</li> </ul> <p><b>General conditions:</b></p> <ul style="list-style-type: none"> <li>signs of dehydration such as nausea, vomiting, muscle cramps, headache, drowsiness, and tiredness. If untreated, mental confusion and fits may develop. Your doctor may need to monitor your blood sodium levels.</li> </ul> |            |

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

### 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](http://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 ACETEC contains

|   |  |
|---|--|
| <b>Active ingredient (main ingredient)</b>      | enalapril maleate 5, 10 or 20 mg per tablet  |
| <b>Other ingredients (inactive ingredients)</b> | <ul style="list-style-type: none"> <li>lactose monohydrate</li> <li>sodium bicarbonate</li> <li>maize starch</li> <li>pregelatinised maize starch</li> <li>magnesium stearate</li> </ul> |

|                            |   |
|----------------------------|---|
|                            | <ul style="list-style-type: none"> <li>iron oxide red (ACETEC 10)</li> <li>Iron oxide brown 70 IC07460 brown (ID: 3792) (ACETEC 20 mg)</li> </ul> |
| <b>Potential allergens</b> | <ul style="list-style-type: none"> <li>Sugars as lactose</li> <li>sulfites</li> </ul>   |

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

### What ACETEC looks like

ACETEC comes in three types of tablets:

- ACETEC 5 mg - White arc triangle shaped biconvex tablet, debossed with "5" over "G" on one side and scoreline on the other side. (AUST R 75497)
- ACETEC 10 mg - Rusty red, arc triangle shaped biconvex tablet, debossed with "10" over "G" on one side and scoreline on the other side. (AUST R 75498)
- ACETEC 20 mg - Peach, arc triangle shaped biconvex tablet, debossed with "20" over "G" on one side and scoreline on the other side. (AUST R 75499)

A box of ACETEC contains 30 tablets.

Not all strengths may be available in Australia.

### Who distributes ACETEC

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

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ACETEC® is a Viatris company trade mark.

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