

ACETEC

Enalapril maleate Tablets 2.5 mg, 5 mg, 10 mg & 20 mg



What is in this leaflet

This leaflet answers some common questions about ACETEC.

It does not contain all 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 ACETEC against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What ACETEC is used for

ACETEC contains the active ingredient enalapril maleate. It 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.

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.

How ACETEC works

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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

ACETEC is not addictive.

Before you take ACETEC

When you must not take it

Do not take ACETEC if you have an allergy to:

- any medicine containing enalapril maleate or any other 'ACE inhibitor' medicine for high blood pressure or heart failure
- any of the 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 ACETEC if you have a history of swelling of the face, lips, tongue, throat, hands or feet, for no apparent reason.

Do not take ACETEC if you have diabetes and are taking a medicine called aliskiren to reduce blood pressure.

Do not take ACETEC if you are also taking medicines that inhibits neprilysin such as sacubitril/valsartan.

Do not take this medicine if you are pregnant or breastfeeding. Your baby may absorb this medicine in the womb or from breast milk and there is a possibility of harm to the baby.

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 it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

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

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. ACETEC should not be used during pregnancy or while breastfeeding.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney disease or are undergoing dialysis
- diabetes
- heart problems
- low blood pressure.

Tell your doctor if you:

- have recently suffered from excessive vomiting or diarrhoea
- are following a very low salt diet
- have surgery or anaesthesia scheduled, as there may be a sudden fall in blood pressure associated with anaesthesia.

If you have not told your doctor about any of the above, tell him/her before you start taking ACETEC.

Taking other medicines

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

Some medicines and ACETEC may interfere with each other. These include:

- medicines used to treat high blood pressure
- diuretic tablets – also called fluid or water tablets
- lithium, a medicine used to treat mood swings and some types of depression
- potassium tablets
- potassium-containing salt substitutes
- potassium-sparing agents (e.g. spironolactone, eplerenone, triamterene, amiloride)
- non-steroidal anti-inflammatory medicines (NSAIDs or Coxibs/COX-2 inhibitors), used to relieve pain, swelling and other symptoms of inflammation
- arthritis medicines including gold therapy
- insulin or oral antidiabetic medicines. You should be closely monitored for low blood glucose levels, especially during the first month of treatment with ACETEC.
- medicines used to prevent organ transplant rejections (e.g. temsirolimus, sirolimus & everolimus).
- Neprilysin inhibitor (e.g. sacubitril, used in combination with valsartan),

medicine used to treat heart problems.

- DPP-IV inhibitors used to treat type 2 diabetes (e.g. vildagliptin).

These medicines may be affected by ACETEC 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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take ACETEC

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

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 as prescribed by your doctor.

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.

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.

How to take it

Swallow the tablets with a full glass of water.

When to take it

Take your medicine at about the same time(s) each day.

Taking it at the same time(s) each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps control your high blood pressure and helps improve your heart failure, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

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

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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, ask your doctor or pharmacist.

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

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much ACETEC. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include dizziness and light-headedness.

While you are using ACETEC

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ACETEC.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

If you feel any light-headedness or dizziness after you take your first dose of ACETEC or if your dose is increased, tell your doctor immediately. This is especially important if you are taking ACETEC for heart failure.

Make sure you drink enough water during exercise and hot weather when you are taking ACETEC, especially if you sweat a lot.

If you have excessive vomiting and/or diarrhoea while taking ACETEC, tell your doctor.

Things you must not do

Do not take ACETEC to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

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

This medicine may cause dizziness and light-headedness in some people especially after the first dose or if the dose is increased. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

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

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. 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 continues or gets worse, talk to your doctor.

Side effects

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

This medicine helps most people with high blood pressure and heart failure, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

- light-headedness or dizziness
- headache
- fatigue
- dry cough
- mild stomach upsets such as feeling sick, diarrhoea, or stomach pains
- muscle cramps.

They are usually mild.

Tell your doctor immediately you notice any of the following:

- changes in the way your heart beats, for example, if you notice it beating faster
- fainting
- yellowing of the skin and eyes, also called jaundice
- itchy skin rash or other skin problems
- signs of worrying or frequent infections such as fever, severe chills, sore throat or mouth ulcers
- passing less urine than is normal for you
- 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.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, stop taking ACETEC and go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- swelling of the hands, feet, or ankles
- pinkish, itchy swellings on the skin, also called hives
- chest pain, angina
- wheeziness due to tightness in the chest
- collapse, numbness or weakness of arms or legs.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

Some of the side effects (for example, changes in blood pressure, potassium levels) can only be found when your doctor does tests from time to time to check your progress.

After using ACETEC

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store ACETEC or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

ACETEC 2.5 mg tablets are white, oval shaped biconvex tablets, debossed with "2.5" scoreline "G" on one side and scoreline on the other side.

ACETEC 5 mg tablets are white arc triangle shaped biconvex tablets, debossed with "5" over "G" on one side and scoreline on the other side.

ACETEC 10 mg tablets are rusty red, arc triangle shaped biconvex tablets, debossed with "10" over "G" on one side and scoreline on the other side.

ACETEC 20 mg tablets are peach, arc triangle shaped biconvex tablets, debossed with "20" over "G" on one side and scoreline on the other side.

Not all strengths may be marketed.

Ingredients

Active ingredient:

ACETEC contains 2.5, 5, 10 or 20 mg of enalapril maleate as the active ingredient.

Inactive ingredients:

ACETEC also contains:

- sodium hydrogen carbonate
- pregelatinized starch
- maize starch
- lactose monohydrate
- magnesium stearate
- iron oxide red (10 mg)
- iron oxide brown (20 mg)

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Acetec is supplied in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland
NEW ZEALAND

Telephone: 0800 579 811

Date of Preparation

11 December 2020
(Based on datasheet dated 11
December 2020)