

Kaluril

amiloride hydrochloride dihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Kaluril.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Kaluril against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What Kaluril is used for

Kaluril is used to:

- decrease swelling (oedema) of the ankles, feet or legs due to certain heart problems
- reduce build-up of fluid in the abdomen (ascites) due to liver disease
- lower high blood pressure (hypertension)

Kaluril is a fluid tablet or diuretic. It reduces the amount of excess fluid in the body by increasing the amount of urine produced. Kaluril helps reduce oedema, fluid build-up and high blood pressure by making your kidneys pass more water and salt.

Kaluril may be taken alone or in combination with other medicines to treat your condition.

It is especially useful when taken together with certain other diuretics, which cause loss of potassium from the body. Unlike these other diuretics, Kaluril retains potassium and is able to maintain a normal potassium level in the blood.

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

Your doctor may have prescribed Kaluril for another reason.

Kaluril is available only with a doctor's prescription.

There is no evidence that Kaluril is addictive.

Before you take Kaluril

When you must not take it

Do not take Kaluril if you have had an allergic reaction to:

- medicines containing amiloride (e.g. Amizide, Midamor, Moduretic)
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take Kaluril if you:

- have severe kidney disease
- are not producing or passing any urine
- have high potassium levels in your blood (hyperkalaemia)
- are following a high potassium diet, or taking potassium tablets

or other potassium-conserving medicines

Check with your doctor or pharmacist if you are not sure about any of the above.

Do not take Kaluril if you are pregnant or intend to become pregnant.

Like most diuretic medicines, Kaluril is not recommended for use during pregnancy.

Do not take Kaluril if you are breastfeeding or plan to breastfeed.

It is not known whether Kaluril passes into breast milk. However, because of the potential harm to the baby, Kaluril is not recommended for use during breast-feeding.

Do not give Kaluril to children.

The safety of Kaluril in children has not been established.

Do not take Kaluril if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date, it may not work as well.

Do not take Kaluril if the packaging shows signs of tampering or the tablets do not look quite right.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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

- diabetes
- kidney problems
- liver problems
- heart and lung problems.

Your doctor may want to take special care if you have any of these conditions.

Tell your doctor if you are following a potassium-rich diet (i.e. eating foods which are high in potassium such as bananas or oranges) or are taking potassium supplements.

Your blood potassium levels may increase too much.

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

Taking other medicines

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

Some medicines may be affected by Kaluril, or may affect how well it works. These include:

- tablets or supplements containing potassium (e.g. Slow-K, Span-K, KSR)
- salt-substitutes which contain potassium
- multivitamin preparations containing potassium
- certain other fluid tablets or diuretics such as spironolactone (Aldactone, Spiractin)
- angiotensin converting enzyme (ACE) inhibitors (e.g. Renitec, Alphapril, Zestril, Prinivil and Lisodur) and angiotensin II receptor antagonists (e.g. Atacand, Cozaar), medicines used to treat high blood pressure and certain heart or kidney conditions
- ciclosporin (e.g. Neoral, Sandimmun) and tacrolimus (Prograf), medicines used to help prevent organ transplant rejection or to treat certain problems with the immune system
- lithium, a medicine used to treat mood swings and some types of depression

- non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen (e.g. Nurofen, Rafen) and diclofenac (e.g. Voltaren, Fenac), medicines used to relieve pain, swelling and other symptoms of inflammation including arthritis
- digoxin (Lanoxin), a medicine used to treat heart failure.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Kaluril.

How to take Kaluril

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist.

How much to take

The usual starting dose is one or two tablets (5 mg or 10 mg) each day.

Your doctor may adjust the dose depending on how well you respond to Kaluril and whether or not you are taking any other medicines.

The maximum dose is four tablets (20 mg) a day.

How to take Kaluril

Swallow the tablets with a glass of water.

When to take Kaluril

Take Kaluril every day at about the same time each day, unless your doctor tells you otherwise.

Taking your tablets at the same time each day will have the best effect on your blood pressure. It will also help you to remember when to take the tablets.

Kaluril can be taken with or without food.

If you are taking Kaluril once a day, take it in the morning, for example, at breakfast time.

Kaluril takes about two hours to start working.

If you are taking more than one dose a day, take the last dose no later than 6 pm, unless your doctor tells you otherwise.

Kaluril may increase the amount of water (urine) you pass and also the number of times you go to the toilet. By taking the last dose no later than 6 pm there may be less chance of your sleep being disturbed.

If you forget to take Kaluril

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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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, ask your doctor or pharmacist.

How long to take Kaluril for

Keep taking Kaluril for as long as your doctor recommends.

Kaluril helps to control your condition but does not cure it. Most people will need to take Kaluril on a long-term basis.

If you take too much Kaluril (overdose)

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

You may need urgent medical attention.

If you take too much Kaluril, you may feel weak, thirsty, tired, confused, dizzy, nauseated (feeling sick). You may also vomit, have muscle cramps or an irregular heart beat.

While you are taking Kaluril

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Kaluril.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Kaluril.

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

Tell your doctor if you have any of the following symptoms:

- excessive vomiting or diarrhoea
- dry mouth, thirst
- weakness, tiredness, drowsiness
- muscle pain or cramps
- irregular heart beat
- passing less urine than normal.

If you experience any of the above symptoms, you may be dehydrated from losing too much water.

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

If you do not drink enough water while taking Kaluril, you may feel

faint, lightheaded or sick. This is because your blood pressure is dropping suddenly. If you continue to feel unwell, tell your doctor.

If you plan to have surgery, including dental surgery, which needs a general anaesthetic, tell your doctor or dentist that you are taking Kaluril.

Your doctor or dentist may advise you to temporarily stop taking Kaluril before surgery to avoid a sudden drop in your blood pressure during the procedure.

If you have to have any blood tests, tell your doctor that you are taking Kaluril.

Visit your doctor regularly so they can check on your progress.

Your doctor may want to check your blood pressure and perform blood tests to check your levels of potassium and other minerals to make sure Kaluril is working properly.

Keep a continuous supply of medicine so you don't run out, especially over weekends or on holidays.

Things you must not do

Do not use salt-substitutes, which commonly contain potassium, in your cooking or at the table.

Your potassium levels may increase too much.

Do not stop taking Kaluril, or change the dose, without checking with your doctor.

Do not use Kaluril to treat any other conditions unless your doctor tells you to.

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

Things to be careful of

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

Kaluril may cause drowsiness, dizziness or lightheadedness in some people. If any of these occur, do not drive, operate machinery or

do anything else that could be dangerous.

Be careful getting up from a sitting or lying position.

Dizziness, lightheadedness or fainting may occur, especially when you get up quickly. Getting up slowly may help. If this problem continues or gets worse, talk to your doctor.

Be careful when drinking alcohol or while taking Kaluril.

Combining Kaluril with alcohol can make you more dizzy or lightheaded.

Be aware of foods, drinks or supplements that have a high potassium content.

Kaluril helps to maintain a normal potassium level in your body. However, if you eat foods or have drinks that are high in potassium this may lead to an increase of potassium in your body, which can be harmful. Your doctor and pharmacist have more information on potassium-rich foods.

Side effects

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

Kaluril is usually well tolerated but it may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

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

- dizziness or lightheadedness
- drowsiness or sleeping problems
- headache

- lack of energy, weakness
- nausea (feeling sick), vomiting, loss of appetite
- diarrhoea or constipation
- heartburn, stomach discomfort or pain
- passing wind
- visual disturbances, nasal congestion
- impotence.

The side effects listed above are usually mild.

Tell your doctor as soon as possible if you notice any of the following:

- very dry mouth or unusual thirst
- muscle cramps, joint pain
- numbness or tingling in the hands or feet
- tremor or shaking
- mental confusion
- pain when passing urine
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bruising or bleeding more easily than normal.

The above list includes serious side effects. You may need urgent medical attention.

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

- chest pain or a feeling of tightness in the chest
- an irregular heart beat or palpitations
- vomiting blood or material that looks like coffee grounds
- bleeding from the back passage, black, sticky bowel motions (stools) or bloody diarrhoea
- rash, itching or hives
- swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.

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

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

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

After taking Kaluril

Storage

Keep Kaluril 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.

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

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

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

Do not store Kaluril or any other medicine in the bathroom or near a sink.

Do not leave Kaluril in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Kaluril, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Kaluril is a round, pale yellow tablet marked "AR" over a line over "5" on one side and "G" on the other.

Each bottle contains 50 tablets.

Ingredients

The active ingredient in Kaluril is amiloride hydrochloride dihydrate.

Each tablet contains 5 mg of amiloride hydrochloride dihydrate.

The tablets also contain:

- lactose monohydrate
- maize starch
- microcrystalline cellulose
- povidone
- magnesium stearate.

The tablets are gluten free.

Supplier

Kaluril is supplied in Australia by:

Alphapharm Pty Limited

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.mylan.com.au

Australian registration number:

AUST R 17652

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