

ASIG

Quinapril hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ASIG.

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 ASIG 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 is ASIG

The name of your medicine is ASIG. The active ingredient is called quinapril hydrochloride.

ASIG belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors.

What ASIG is used for

ASIG is used to treat:

- High blood pressure (hypertension)
- Heart failure

Hypertension

ASIG is used to lower high blood pressure (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, including stroke, heart disease and kidney failure.

If your blood pressure is too high, ASIG can help lower it to normal levels.

Heart Failure

Heart failure means that the heart muscle is weak and 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. 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.

How ASIG works

ASIG works by widening your blood vessels, which reduces pressure in the vessels, making it easier for your heart to pump blood around your body. This helps increase the supply of oxygen to your heart so that when you place extra demands on your heart, such as during exercise, your heart may cope better and you may not get short of breath as easily.

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

ASIG is not addictive.

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

Before you take ASIG

When you must not take it

Do not take ASIG if:

- **You have an allergy to ASIG or any other product containing quinapril or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction to ASIG may

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

- **You have taken any other ACE Inhibitor medicine before, which has caused your face, lips, tongue, throat, hands or feet to swell, 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 ASIG.

- **You have a history of swelling of the face, lips, tongue, throat, hands or feet for no apparent reason.**
- **You have kidney problems or a condition called “renal artery stenosis”.**
- **You have regular dialysis for blood filtration.** You may have an allergic reaction.

Do not take ASIG if you are pregnant.

ASIG may affect your developing baby if you take it during pregnancy.

Do not take ASIG if you are breastfeeding.

ASIG may pass into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

Do not take ASIG 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 ASIG, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to:

- Any other medicines
- Any other substances, such as foods, preservatives or dyes

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

- Kidney problems, or you are having dialysis
- Liver problems
- Heart problems
- Low blood pressure, which you may notice as dizziness or light-headedness
- Diabetes
- High levels of potassium in your blood

You must also tell your doctor if you:

- have a family history of swelling of the face, lips, tongue, throat, hands or feet.
- you are also taking an anti-inflammatory (NSAID or COX-2 inhibitor) and a thiazide diuretic.
- are following a very low salt diet.
- are about to receive desensitisation therapy for an allergy.
- are about to have surgery or a general anaesthetic
- plan to become pregnant or breastfeed

If you have not told your doctor about any of the

above, tell them before you start taking ASIG.

Taking other medicines

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

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

- Other medicines used to treat high blood pressure
- Diuretics, also known as fluid or water tablets
- Nonsteroidal anti-inflammatory drugs (NSAID's), medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- Potassium supplements or potassium-containing salt substitutes (check food labels)
- Lithium, a medicine used to treat mood swings and some types of depression
- Tetracycline antibiotics

These medicines may be affected by ASIG, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

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

Use in Children

The safety and effectiveness of ASIG for use in children has not been established.

How to take ASIG

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

They may differ from the information contained in this leaflet.

Your doctor or pharmacist will tell you how many tablets you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

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

How much to take

For High Blood Pressure

For most patients, not on diuretics, the usual starting dose is 5-10 mg taken once a day. The dose may need to be increased depending on your blood pressure at an interval of 4 weeks. Most patients take between 10 mg and 40 mg each day. This dose may be taken once a day or divided into two equal doses per day.

For Heart Failure

The usual starting dose is 5 mg taken once a day. In most patients, effective doses are between 10 mg and 20 mg a day. Your doctor will advise you whether the dose is to be taken as a single dose or as two separate doses.

How to take it

Swallow ASIG whole with a full glass of water. Do not chew the tablets.

When to take it

Take ASIG at about the same time each day.

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

Take ASIG before meals. Food with a high fat content may interfere with the absorption of ASIG.

How long to take it

Continue taking your medicine for as long as your doctor tells you. ASIG helps control your condition, but does not cure it. Therefore you must take it every day.

Do not stop taking it without first checking with your doctor.

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

You may need urgent medical attention.

If you take too much ASIG, you may feel light-headed, dizzy or you may faint.

While you are taking ASIG

Things you must do

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking ASIG.

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

If you do not drink enough water while taking ASIG, you may feel faint, light-headed or sick. This is because your blood pressure is dropping suddenly. If you continue to feel unwell, tell your doctor.

If you suffer from vomiting and/or diarrhoea while taking ASIG, tell your doctor.

You may lose too much water and salt and your blood pressure may drop too much.

If you feel light-headed or dizzy after your first dose or if your dose of ASIG is increased, tell your doctor immediately.

This is especially important if you are taking ASIG for heart failure.

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

Your blood pressure may drop suddenly.

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

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

ASIG may interfere with the results of some tests.

Have your blood pressure checked when your doctor says, to make sure ASIG is working properly.

Go to your doctor regularly for a check-up.

Your doctor may occasionally do a blood test to check your potassium levels and see how your kidneys are working.

Things you must not do

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

Do not take ASIG to treat any other complaints unless your doctor or pharmacist tells you to.

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

Things to be careful of

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. See your doctor if this problem continues or gets worse.

Take care driving, operating machinery or doing anything else that could be dangerous until you know how ASIG affects you.

As with other ACE inhibitor medicines, ASIG may cause dizziness, light-headedness, or tiredness in some people. Make sure you know how you react to ASIG before you drive a car, operate machinery, or do any thing else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive.

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

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.
- **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.

- **Diet:** eat a healthy low-fat diet that includes plenty of fresh vegetables, fruit, bread, cereals and fish. Also eat less fat and sugar.
- **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.
- **Exercise:** regular exercise helps to reduce blood pressure and helps get the heart fitter, but it is important not to overdo it. Walking is good exercise, but try to find a route that is reasonably flat. Before starting any exercise, ask your doctor about the best kind of program for you.
- **Smoking:** your doctor may advise you to stop smoking or at least cut down. There are enormous benefits to be gained from giving up smoking.

Side effects

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

ASIG helps most people with hypertension 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

treatment if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

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

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

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

- Feeling light-headed, dizzy or faint
- Dry cough
- Headache
- Feeling sick (nausea) or vomiting
- Stomach pain
- Diarrhoea
- Constipation
- Aching, tender or weak muscles not caused by exercise
- Unusual tiredness or weakness, fatigue
- Feelings of deep sadness and unworthiness (depression)
- Hair loss or thinning
- Dry mouth or throat
- Taste disturbances or loss of taste
- Confusion or nervousness
- Back pain
- Rash
- Difficulty in getting or maintaining an erection

These side effects are usually mild.

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

- Disturbed vision
- Symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal
- Itchy, raised or red skin rash
- Fast or irregular heart beat
- Shortness of breath or tightness in the chest
- Frequent infections such as fever, severe chills, sore throat or mouth ulcers
- Severe upper stomach pain, often with nausea and vomiting
- Passing little or no urine
- Bleeding or bruising more easily than normal

These may be serious side effects. You may need medical attention. Serious side effects are rare.

If any of the following happen, stop taking ASIG and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- Fainting within a few hours of taking a dose
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- Severe flaking or peeling of the skin
- Severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- Chest pain

These are very serious side effects. You may need urgent

medical attention or hospitalisation. These side effects are very rare.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After using ASIG

Storage

Keep your tablets in the pack until it is time to take them. If you take the tablets out of the pack they will not keep well.

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

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

Do not leave it on a windowsill or in the car on hot days.

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

Product description

What it looks like

ASIG comes in three strengths:

- ASIG 5 mg tablets: Reddish-brown, film-coated, oval tablet scored on both sides and marked “5” on both sides in opposite direction,
- ASIG 10 mg tablets: Reddish-brown, film-coated, triangular tablet, scored on both sides and marked “10” on one side,
- ASIG 20 mg tablets: Reddish-brown, film-coated, round tablet, scored on both sides and marked “20” on one side.

They are available in packs of 30 tablets.

Ingredients

Active ingredient:

- ASIG 5 mg: each tablet contains 5 mg of quinapril hydrochloride
- ASIG 10 mg: each tablet contains 10 mg of quinapril hydrochloride
- ASIG 20 mg: each tablet contains 20 mg of quinapril hydrochloride

Other ingredients:

ASIG tablets also contain the following excipients:

- Magnesium carbonate
- Lactose
- Gelatin
- Crospovidone
- Magnesium stearate
- Candelila wax
- Opadry Y-5-0920

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

The Australian Registration numbers are:

ASIG 5mg, AUST R 42722
ASIG 10mg, AUST R 42724
ASIG 20mg, AUST R 42723

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