

Monace

fosinopril sodium

CONSUMER MEDICINE INFORMATION

What is in this leaflet

Please read this leaflet carefully before you start taking Monace tablets.

This leaflet answers some common questions about Monace tablets.

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 Monace tablets 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 Monace is used for

Monace is used for treating high blood pressure (hypertension) or heart failure. Both of these are long term (chronic) diseases so it is important that you continue to take your Monace tablets every day.

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.

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 Monace tablets work

Monace contains fosinopril sodium. Fosinopril sodium belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors.

It works by widening your blood vessels, reducing the pressure in the vessels (reducing 'blood pressure') and by making it easier for your heart to pump blood around your body. This helps your heart to work better

by increasing the supply of oxygen to your heart.

Your doctor may have prescribed Monace for another reason.

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

Monace is not addictive.

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

Use in children

The safety and effectiveness of Monace in children has not been established.

Before you take Monace

When you must not take it

Do not take Monace tablets if:

- you are allergic to any other medicines containing fosinopril sodium (the active ingredient in Monace), or to any of the inactive ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction 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 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 Monace.

- you have a history of angioedema or angioneurotic oedema, which is swelling of the face, lips, tongue, throat (which may cause difficulty in breathing or swallowing), hands or feet, for no apparent reason.
- you are using ACE inhibitors with aliskiren-containing products

Do not take Monace tablets if you are pregnant or trying to become pregnant.

Monace may cause serious injury to your developing baby if you take it during pregnancy.

Do not take Monace tablets if you are breastfeeding or intend to breastfeed.

Do not take Monace tablets after the expiry date (EXP.) printed on the pack.

Do not take Monace tablets 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 Monace, 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 a family history of swelling of the face, lips, tongue, throat that may cause difficulty in breathing and swallowing.

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

- diabetes
- take any other medicines including any immunosuppressant medicines or trimethoprim containing medicines

- kidney problems, or have had kidney problems in the past, or are having dialysis
- liver problems, or have had liver problems in the past
- low blood pressure, which you may notice as dizziness or lightheadedness
- are going to have surgery (including dental surgery) involving a general anaesthetic, even if it is minor

Tell your doctor if you are pregnant or plan to become pregnant or breastfeed.

If you have not told your doctor about any of the above, tell them before you start taking Monace.

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 may affect the way Monace works. It is especially important that you tell your doctor if you are taking any of the following:

- diuretics, also known as fluid or water tablets (for example Lasix[®], Urex[®], Natrilix[®], Moduretic[®])
- lithium or lithium containing preparations (for example Lithicarb[®], Priadel[®])
- potassium tablets (for example SPAN-K[®], SLOW-K[®] or MAG-K[®])
- potassium-containing salt substitutes (for example PRESSOR-K[®])
- antacids, medicines used to treat heartburn and indigestion
- medicines used to treat diabetes (such as insulin, sulphonylurea and vildagliptin)
- aspirin
- anti-inflammatory medicines (those that are used to relieve pain, swelling and other

symptoms of inflammation, including arthritis) and include non-steroidal anti-inflammatory drugs (NSAIDs (for example Voltaren[®], Indocid[®]) and COX-2 inhibitors (for example Celebrex). Taking a combination of Monopril with a thiazide diuretic (fluid tablet) and an anti-inflammatory medicine may damage your kidneys.

- medicines that lower your immune system, such as medicines used to prevent rejection of transplant organs.
- trimethoprim containing medicines (for example Bactrim, Septrim, Alprim) used to treat certain types of infections.

If you are taking Monace for high blood pressure do not take any medicine (including ones bought without prescription) for appetite control, asthma, colds, coughs, hayfever or sinus problems unless you have discussed the medicine with your doctor or pharmacist.

These medicines may be affected by Monace, 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 avoid while taking Monace.

How to take Monace

Follow all directions given to you by your doctor and 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.

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

How much to take

Monace is usually taken at a dose of 10mg to 40mg once a day. Your doctor may have prescribed a different dose for you.

When to take it

Take Monace 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.

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

If you need to take an antacid, take it at least 2 hours before or 2 hours after your dose of Monace.

How long to take it

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

If you forget to take Monace

If you have forgotten to take your dose of Monace tablets take your next dose at the normal time and in the normal amount.

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

Do not take a double dose to make up for the dose that you missed. Do not take any more than what your doctor has prescribed for you.

If you are not sure what to do or have any questions, ask your doctor or pharmacist. If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much Monace (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 Monace. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Monace

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Monace.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Monace. Tell your doctor if you have excessive vomiting or diarrhoea or experience any of the following symptoms:

- light-headed, dizzy or faint
- dry mouth or thirst
- weakness, tiredness or drowsiness
- fast heart beat
- passing less urine than normal
- muscle pain or cramps

If you experience these symptoms, you may be dehydrated because you are losing too much water.

This is more likely to occur when you begin to take Monace or if your dose is increased.

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

If you do not drink enough water while taking Monace, your blood pressure may drop suddenly and you may dehydrate. If you experience any of the above symptoms, tell your doctor.

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

Having a general anaesthetic while taking Monace may also cause your blood pressure to drop suddenly.

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

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

Monace may interfere with the results of some tests.

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

Go to your doctor regularly for a check-up.

Your doctor may occasionally do a blood test to see how the Monace is affecting you.

Things you must not do

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

Do not use Monace to treat any other conditions unless your doctor or pharmacist tells you to.

Do not stop taking Monace or lower the dose, without checking with your doctor.

Things to be careful of

As with other ACE inhibitor medicines, you may feel light-headed or dizzy when you begin to take Monace or after your dose is increased. This is because your blood pressure is dropping suddenly.

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. Be careful the first time you take Monace, especially if you are elderly.

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

Monace may cause drowsiness, dizziness or lightheadedness in some people and affect alertness.

Make sure you know how you react to Monace before you drive a car, operate machinery, or do anything 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

- **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 which 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 programme for you.
- **Smoking**
 - your doctor may advise you to stop smoking or at least cut down.

Side effects

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

Monace helps most people with high blood pressure, 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.

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
- upset stomach (dyspepsia) or heartburn
- diarrhoea
- muscle cramps
- pain in the joints
- unusual tiredness or weakness, fatigue

These are the more common side effects of Monace. (Mostly these are mild and short-lived.)

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

- changes to your heart rhythm
- infections of your urinary tract or upper respiratory tract (URTI, or cold or flu symptoms)
- severe dizziness (vertigo)
- impotence (inability to get or maintain an erection)
- mild rash or itching
- gout (painful, swollen joints)

- diabetes (symptoms include - excessive thirst, greatly increased amount of urine, increase of appetite with a loss of weight, feeling tired, drowsy, weak, depressed, irritable and generally unwell)
- sore throat and fever
- hepatitis (symptoms include - nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes and dark coloured urine)
- confusion; irregular heartbeat; nervousness; numbness or tingling of the hands, feet or lips; shortness of breath or difficulty breathing; weakness or heaviness of legs. (You may experience these symptoms if too much potassium builds up in your body.)

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

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

- swelling of the face, lips, mouth, throat, hands and feet
- difficulty in breathing
- feeling faint or if skin turns yellow
- sore throat and fever
- chest pain
- itchy skin and/or rash
- not urinating (passing water) as much as usual
- stomach pain with or without nausea

These are very serious side effects. You may need urgent medical attention or hospitalisation.

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 taking Monace

Storage

Keep your tablets in the blister 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°C.

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

Do not leave it on a window sill 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 tells you to stop taking Monace, 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

Monace tablets are available in two strengths: -

- Monace 10 - white to off-white, arc-rectangular shaped, with "G|G" on one side and "FS|10" on the other side.
- Monace 20 - white to off-white, capsule shaped, with "G|G" on one side and "FS|20" on the other side.

Monace 10 mg and 20 mg tablets are available in blister packs of 30 tablets.

Ingredients

The active ingredient in Monace is Fosinopril sodium.

Each Monace 10 tablet contains 10 mg of Fosinopril sodium.

Each Monace 20 tablet contains 20 mg of Fosinopril sodium.

The tablets contain the following inactive ingredients:

- microcrystalline cellulose
- sodium starch glycollate
- pregelatinised maize starch
- hydroxypropylcellulose
- ethanol
- crospovidone
- glyceryl behenate

Monace tablets also contain traces of benzoates and sulfites.

Manufacturer/Supplier

Monace is supplied by:

Alphapharm Pty Limited

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

Monace 10 Blister - AUST R 101878

Monace 20 Blister - AUST R 101901

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