

HYFORIL® 10/12.5 mg and HYFORIL® 20/12.5 mg

fosinopril + hydrochlorothiazide Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about HYFORIL 10/12.5 mg and HYFORIL 20/12.5 mg (fosinopril + hydrochlorothiazide 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 risks and benefits. Your doctor has weighed the risks of you taking HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg against the benefits it is expected to have for you.

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

Keep this leaflet with this medicine.

You may need to read it again.

What HYFORIL 10/12.5 mg and HYFORIL 20/12.5 mg are used for

HYFORIL 10/12.5 mg and HYFORIL 20/12.5 mg contain two medicines, fosinopril sodium and hydrochlorothiazide. Both medicines reduce blood pressure, but work in different ways. Fosinopril belongs to the class of medicines called Angiotensin Converting Enzyme (ACE) inhibitors that act on the heart and blood vessels. Hydrochlorothiazide is a diuretic, i.e., it works by making your kidneys pass more water and salt. Together fosinopril and hydrochlorothiazide lower high blood pressure.

Your doctor would have prescribed HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg (fosinopril + hydrochlorothiazide tablets) for the following:

- **treatment of high blood pressure if treatment of high blood pressure is not satisfactory with fosinopril alone.**

Fosinopril and hydrochlorothiazide tablets are not suitable for initial therapy of high blood pressure.

Your doctor may prescribe HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg for another reason. Ask your doctor if you have any questions about why HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg has been prescribed for you.

There is no evidence that HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg tablets are addictive.

Fosinopril + hydrochlorothiazide may affect your ability to drive a car or operate machinery.

Before you take HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg

When you must not take it

Do not take HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg if you are allergic to fosinopril (or other ACE inhibitors) or hydrochlorothiazide (or other thiazides) or sulphonamides (possible cross-reaction) or to any of the tablet ingredients at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching, shortness of breath, swelling of the tongue or face.

Do not take if any of the following applies to you:

- **You have a condition known as angioneurotic oedema that manifests with swelling of face, lips, hands/feet, or breathing difficulties.**
- **You are not producing urine (anuric).**

- **You are pregnant, or planning to become pregnant, or are breast-feeding currently.**

Do not take HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg after the expiry date printed on the pack.

If you take it after the expiry date has passed, it may not work as well or may cause harm. Do not take HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg if the tablets do not look quite right.

Do not take HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you have any allergies to:

- **any other medicines containing ACE inhibitors or any thiazide group of diuretics or sulphonamides**
- **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 swallowing or breathing.

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

Like many other medicines, HYFORIL 10/12.5 mg and HYFORIL 20/12.5 mg may affect your developing baby if you take it during pregnancy. Your baby may absorb this medicine in the womb and therefore there is a possibility of harm to the baby.

If it is necessary for you to take HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg, your doctor can help you decide whether or not to take it during pregnancy.

Tell your doctor if you are breast-feeding or planning to breast-feed.

Your baby may absorb this medicine from breast milk and therefore there is a possibility of harm to the baby. Your doctor will discuss the possible risks and benefits of using HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg during breast-feeding.

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

- **You have been diagnosed to have conditions known as systemic lupus erythematosus or scleroderma.**
- **You have a condition known as gout (problem with your joints).**
- **You are dehydrated (e.g. have had diarrhoea and/or vomiting recently).**
- **You have sugar diabetes (diabetes mellitus).**
- **You have problems with your kidney(s) and/or liver.**
- **You have very high blood pressure at the start of treatment.**
- **You are on a low salt diet.**
- **You are an elderly person (more than 65 years of age).**
- **You have problems with the performance of your heart.**
- **You have been diagnosed to have a condition known as renal artery stenosis.**
- **You have had a kidney transplant or are on haemodialysis.**
- **You have been told by your doctor that you have abnormal levels of electrolytes (increased or decreased levels of sodium, potassium or chloride) in your blood.**

- **You are about to have a treatment called LDL apheresis.**
- **You are going to have desensitisation treatment (e.g. treatment to reduce the effects of an allergy to bee or wasp stings).**
- **You are going to have surgery (including dental surgery) involving a general anaesthetic, even if it is minor.**

HYFORIL 10/12.5 mg and HYFORIL 20/12.5 mg tablets are not recommended for use in children.

Avoid alcoholic beverages until you have discussed their use with your doctor.

Your medicine also contains small amounts of an inactive ingredient called anhydrous lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Tell your doctor if you plan to have a blood/urine test.

If you need a laboratory investigation such as blood test or urine test, do inform your doctor about the medicine you are taking.

If you have not told your doctor about any of the above, tell them before you take HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg.

Taking other medicines

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

Some medicines may interfere with the absorption or action of fosinopril + hydrochlorothiazide.

- **Antacids (medicines used to relieve heartburn, indigestion). These products can reduce the absorption of fosinopril. If it is essential that you take these products, it is recommended that ingestion of fosinopril and hydrochlorothiazide tablets and antacids be separated by at least 2 hours.**
- **Barbiturates (sedative drugs which may be used in the treatment of sleeplessness or epilepsy)**
- **Benzodiazepines (such as midazolam used as tranquilizers).**
- **Medicines containing calcium salts**
- **Cholesterol lowering medicines (eg colestyramine or colestipol)**
- **Cimetidine (a medicine for a type of digestive disorder)**
- **Cyclosporin or tacrolimus (used following organ transplants for immunosuppression)**
- **Excess of common table salt**
- **Corticosteroids (used to treat various conditions including rheumatism, arthritis, allergic conditions, certain skin diseases, asthma or certain blood disorders)**
- **Hypnotics (eg diazepam)**
- **Anaesthesia-inducing medicines**
- **Isoniazid (antibacterial agent used to treat an infection called tuberculosis)**
- **Lithium (used in treatment of certain mental illnesses)**

- Medicines called catecholamines [ephedrine, noradrenaline or adrenaline; drugs used for treatment of low blood pressure, heart failure, asthma or allergies (noradrenaline and adrenaline are always given under medical supervision)]
- Medicines that relax muscles (eg tizanidine)
- Medicines used to prevent blood from clotting normally (warfarin or coumarin drugs)
- Medicines used to treat certain heart conditions (eg digoxin)
- Medicines used to treat gout (allopurinol used for treatment of gout)
- Methyldopa (used for treatment of high blood pressure)
- Narcotics (morphine like medicines to reduce pain)
- Other blood pressure lowering medicines e.g. diuretics (furosemide), beta-blockers (atenolol); nitrates (e.g. isosorbide mononitrate, nitroglycerine), vasodilators (e.g. hydralazine, nifedipine, amlodipine), barbiturates (eg phenobarbitone), phenothiazines (eg chlorpromazine), tricyclic antidepressants (eg amitriptyline) or alcohol
- Pain relievers known as Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) (e.g. ibuprofen, aspirin)
- Phenytoin, valproic acid (used to treat convulsions)
- Potassium supplements or potassium containing salt substitutes
- Sugar diabetes medicines (such as oral hypoglycaemic agents or insulin)
- Water tablets especially the ones that prevent loss of potassium in urine (e.g. spironolactone, amiloride, triamterene)

These medicines may be affected by fosinopril + hydrochlorothiazide, or may affect how well it works. You may need to use different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist will be able to tell you what to do when taking/being given HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg tablets with other medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg tablets.

How HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg is given

How much to take

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

Take your medicine as instructed by your doctor. Do not take more than the doctor told you to. Check the label carefully for how much to take and how often to take. Your pharmacist or doctor can help if you are not sure.

How to take it

Swallow the tablet whole with a glass of water. HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg tablets may be taken with or without food.

Adults

The usual starting dose is one HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg (fosinopril + hydrochlorothiazide 10 + 12.5 mg or fosinopril + hydrochlorothiazide 20 + 12.5 mg) tablet taken once daily. Your daily dose will depend on your condition and your response to treatment.

HYFORIL 10/12.5 mg and HYFORIL 20/12.5 mg tablets are not recommended if you have severe kidney problems.

When to take it

Take your HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg tablets at about the same time everyday. Taking your tablets at the same time will have the best effect. It will also help you to remember when to take the tablets.

If you need to take an antacid, take it at least 2 hours before or two hours after your dose of HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg.

How long to take it

Continue taking HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg tablets until your doctor tells you to stop. HYFORIL 10/12.5 mg and HYFORIL 20/12.5 mg help to control your condition but does not cure it. Therefore you must take HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg every day. Continue taking it for as long as your doctor tells you.

Do not stop taking HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg tablets because you begin to feel better

Do not stop taking HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg, or lower the dosage, without checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Stopping HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg without doctor's advice may worsen your condition. Your doctor will decide when you should stop taking it.

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, then go back to taking it as you would normally.

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

If you are not sure what to do, 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 (Overdose)

Immediately telephone your doctor, or the Poisons Information Centre on 13 11 26 for advice on the management of overdose or go to Emergency department at your nearest hospital, if you think that you or anyone else has taken too much of HYFORIL 10/12.5 mg or 20/12.5 mg tablets. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Keep these telephone numbers handy.

While you are using HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg

Things you must remember

Take HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg tablets exactly as your doctor tells you to.

Try not to miss any doses and take the medicine even if you feel well.

Visit your doctor regularly for check ups.

Tell all doctors, dentists and pharmacists who are treating you that you are taking HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg tablets.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg tablets.

Tell your doctor if you are to undergo any blood or urine test.

If you become pregnant while taking HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg tablets, tell your doctor immediately.

Things you must do

Tell your doctor if you have excessive vomiting or diarrhoea or experience any of the following symptoms:

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

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 HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg or if your dose is increased.

Make sure you drink enough water during exercise and hot weather when you are taking HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg, especially if you sweat a lot.

If you do not drink enough water while taking HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg, 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 HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg.

Having a general anaesthetic while taking HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg may also cause your blood pressure to drop 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 HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg, especially if you are elderly.

Be careful driving or operating machinery until you know how HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg affects you.

As with other ACE inhibitor medicines, HYFORIL 10/12.5 mg and HYFORIL 20/12.5 mg may cause dizziness, or light-headedness in some people. Make sure you know how you react to your medicine 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 you must not do

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

Do not use HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg tablets to treat any other complaints unless your doctor tells you to.

Do not stop taking HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg tablets, or lower the dose, without first 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 HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg or after your dose is increased. This is because your blood pressure is dropping suddenly.

If you have a pre-existing kidney problem you should follow up regularly with your doctor.

Things that would be helpful for your blood pressure

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, 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 to 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 HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg.

Ask your doctor or pharmacist any questions you may have.

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

- **Feeling sick (nausea), being sick (vomiting), constipation, diarrhoea (loose stools), pain in the belly, indigestion, wind (flatulence), increased or decreased appetite, dryness of mouth, altered taste, increased thirst, ulceration in the mouth, burping, heart burn, difficulty in swallowing**
- **Headache, tiredness, generalized weakness, aches and pain, chills, shivers, dizziness, sleep disturbances, hot flushes, flushing, flu-like symptoms, weight loss**
- **Depressed mood, loss of memory, sleep disturbances, labile mood, drowsiness, confusion, behavioral change, mood swings, restlessness**
- **Pins and needles sensation, numbness, weakness of the extremities**

- **Blurred vision, visual disturbances, yellowish hue in vision (manifestation of a condition called xanthopsia, also called distortion of color vision)**
- **Increased urination, pain in the loin**
- **Vaginal bleeding**
- **Sexual dysfunction**
- **Foul-smelling breath**
- **Increased blood pressure**
- **Diminished hearing, ear infection, ringing in the ears**
- **Muscle cramps, spasm and pain, restricted mobility, joint pains**
- **Pain in the tendons**
- **Runny or stuffy nose, sore throat, cough, difficulty in breathing**
- **Urinary disturbances (associated with burning sensation or pain on passing urine)**
- **Excessive sweating**
- **Increased sensitivity to light**
- **Sexual inability in males**
- **Enlarged glands**
- **Hoarseness of voice**

These are the more common side effects of fosinopril + hydrochlorothiazide. These side effects are usually mild and occur at the start of treatment.

Tell your doctor immediately if you notice any of the following

- **Unusual bleeding or increased tendency to bleed, persistent sore throat and frequent infections, and/or anaemia**
- **Yellowing of skin and whites of eyes with decreased appetite**
- **Irregular heart beat**
- **Pain and distension of the belly with no passage of wind or motions and being sick (vomiting) (manifestations of a condition called intestinal obstruction)**
- **Feeling faint and lightheaded on change of posture**
- **Chest pain and or chest infection**
- **Bleeding from the nose**
- **Swelling of face, ankles or other parts of the body, with sudden increase or decrease in the amount of urine passed or have passed dark coloured urine**
- **Sudden onset of severe abdominal pain with vomiting (manifestations of a condition called pancreatitis)**
- **Awareness of heart beat**
- **Angina (feeling of tightness, heaviness, dull discomfort, or crushing pain that is felt behind the breastbone and may spread to the arms, neck and jaw. It is often brought on by exercise, eating, or stress; or may occur at rest. Angina occurs due to narrowing of blood vessels which supply the muscles of the heart, and the resulting failure to deliver enough oxygen for normal functioning of the heart)**
- **Myocardial Infarction (chest pain is more severe and prolonged than angina pain described above and may be associated with nausea (feeling sick), vomiting (being sick) and excessive sweating (occurs due to a complete blockade in one or more of the blood vessels, which supply the muscles of the heart, and the resulting failure to deliver oxygen for normal functioning of the heart)**

- **Sudden onset of a severe headache, dizziness, numbness/weakness in the face, arm, or leg, especially on one side of the body (or) altered speech and mental ability to understand, disturbed vision in one or both eyes, and loss of balance or coordination** These symptoms may be short-lasting and reversible ("transient ischaemic attack") or may continue ("stroke")

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

- **Some of the symptoms of an allergic reaction may include rashes, hives, itching, chest constriction, shortness of breath or swelling of face, lips, tongue, hands/feet, fainting, dizziness.**
- **Severe skin reactions with blisters, sores or ulceration**

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

Changes in the laboratory tests

- **Abnormal liver function tests**
- **Increase in number of a type of cells in blood called eosinophils**
- **Abnormal deposits in urine**
- **Altered levels of electrolytes sodium and potassium**
- **Increased blood levels of uric acid/ glucose/ cholesterol/ triglycerides**
- **Abnormal kidney function tests**

Some side effects have been reported with the use of other ACE inhibitors and may also occur with the use of HYFORIL. One of these is psychiatric reactions (mental illness with strange or disturbing thoughts) like hallucinations (seeing, feeling, or hearing things that are not there.)

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

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

You may not experience any of them.

After using it

Storage

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

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

Keep your HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg in a cool, dry place where it stays below 25°C.

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

Do not leave it in the car on hot days.

Heat and dampness can destroy some medicines.

Keep this medicine where young children cannot reach it.

Disposal

If your doctor tells you to stop taking HYFORIL 10/12.5 mg or HYFORIL 20/12.5 mg tablets or you find that they have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

HYFORIL 10/12.5 mg tablets are white to off-white, circular tablets, debossed with 'RC3' on one side and plain on the other side. Available in packs of 30 tablets.

HYFORIL 20/12.5 mg tablets are white to off-white, flat beveled edged, circular tablets, debossed with 'FHI' on one side and plain on the other side. Available in packs of 30 tablets.

Ingredients

Active ingredient:

HYFORIL 10/12.5 mg tablets contains 10.0 mg of fosinopril sodium & 12.5 mg of hydrochlorothiazide.

HYFORIL 20/12.5 mg tablets contains 20.0 mg of fosinopril sodium & 12.5 mg of hydrochlorothiazide.

Inactive ingredients:

Anhydrous lactose, crospovidone, povidone, microcrystalline cellulose, colloidal anhydrous silica, purified talc.

Sponsor

HYFORIL is supplied in Australia by:

Ranbaxy Australia Pty Limited

Suite 4.02, Level 4, Building D

12 - 24 Talavera Rd

North Ryde, NSW 2113

Australia

Australian Registration Numbers

HYFORIL 10/12.5 mg tablets blister pack:

AUST R 124585

HYFORIL 20/12.5 mg tablets blister pack:

AUST R 124589

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