

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about DOLAPRIL.

It does not contain all of 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 DOLAPRIL against the benefits they expect it will have 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 DOLAPRIL is used for

DOLAPRIL is used to treat:

- high blood pressure (hypertension)
- some patients who have had a heart attack.

Hypertension

DOLAPRIL 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 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 Attack

A heart attack occurs when one of the major blood vessels supplying blood to your heart becomes blocked. This means that your heart can not receive the oxygen it needs and becomes damaged. This may lead to further problems, such as heart failure, irregular heart rhythms and blood clots.

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

DOLAPRIL 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 lower blood pressure and increase the supply of blood and oxygen to the heart. By increasing the supply of oxygen to your heart, your heart does not have to work as hard which may reduce the risk of further damage to your heart after you have had a heart attack.

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

DOLAPRIL is not addictive.

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

Before you take DOLAPRIL

When you must not take it

Do not take DOLAPRIL if you are allergic to trandolapril, or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to DOLAPRIL may include skin rash,

itchiness, shortness of breath, swelling of the face, lips, tongue, throat, hands or feet.

Do not take DOLAPRIL if 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 breath.

If you have had an allergic reaction to an ACE inhibitor before, you may be allergic to DOLAPRIL.

Do not take DOLAPRIL if you have a history of swelling of the face, lips, tongue, throat, hands or feet, for no apparent reason.

Taking DOLAPRIL could cause this problem to happen again.

Do not take DOLAPRIL if you are undergoing haemodialysis or having your blood treated outside your body.

Taking DOLAPRIL could cause an allergic reaction.

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

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

Do not take DOLAPRIL if you are breastfeeding.

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

Do not give DOLAPRIL to children.

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

Do not take DOLAPRIL if the packaging is torn or shows signs of tampering.

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

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:

- kidney problems
- regular dialysis, blood filtration or other similar procedures
- liver problems
- heart problems
- low blood pressure, which you may notice as dizziness or light-headedness
- high levels of potassium in your blood
- diabetes
- connective tissue disease.

Tell your doctor if you have a family history of swelling of the face, lips, tongue, throat, hands or feet.

Tell your doctor if you are following a very low salt diet.

Tell your doctor if you are about to receive desensitisation therapy for an allergy.

Tell your doctor if you are scheduled to have surgery under general anaesthetic.
Your blood pressure may drop.

Tell your doctor if you plan to become pregnant or breastfeed.
DOLAPRIL should not be used during pregnancy or while breastfeeding.

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

Taking other medicines

Tell your doctor 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 DOLAPRIL may interfere with each other.

These include:

- other medicines used to treat high blood pressure
- diuretics, also known as fluid or water tablets
- some medicines used to treat arthritis, pain or fever
- potassium supplements, large amounts of salt or potassium-containing salt substitutes
- lithium, a medicine used to treat mood swings and some types of depression
- antacids, used to treat heartburn and reflux
- medicines which lower the body's resistance to disease.

These medicines may be affected by DOLAPRIL, 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 have more information on medicines to be careful with or avoid while taking DOLAPRIL.

How to take DOLAPRIL

How much to take

Follow all directions given to you by your doctor and pharmacist carefully.
They may differ from the information contained in this leaflet.

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

The usual dose is one or two capsules taken once daily, up to a maximum of 4 mg once daily.

The usual starting dose for older people (over 65 years) is less than that for younger adults. Your doctor will adjust the dose of DOLAPRIL, depending on how quickly your kidneys and liver can remove it from your body.

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

How to take it

Swallow DOLAPRIL whole with a glass of water.

When to take it

Take DOLAPRIL at about the same time each day.

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

It does not matter if you take DOLAPRIL before, during or after food.

How long to take it

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

If you forget to take DOLAPRIL

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 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 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 you or anyone else may have taken too much DOLAPRIL. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much DOLAPRIL, you may feel light-headed, dizzy, weak, have heart palpitations or faint.

While you are taking DOLAPRIL

Things you must do

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

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

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

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

If you have excessive vomiting or diarrhoea while taking DOLAPRIL 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 taking your first dose of DOLAPRIL, or when your dose is increased, tell your doctor immediately.

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

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

Your blood pressure may drop suddenly.

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

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

DOLAPRIL may interfere with the results of some tests.

Have your blood pressure checked when instructed by your doctor, to make sure DOLAPRIL is working.

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 DOLAPRIL to anyone else, even if they have the same condition as you.

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

Do not stop taking DOLAPRIL, 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 out of 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.

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

As with other ACE inhibitors, DOLAPRIL may cause dizziness, light-headedness or tiredness in some people. Make sure you know how you react to DOLAPRIL before you drive, 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.

Side effects

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

DOLAPRIL helps most people with hypertension and some heart conditions, 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:

- light headedness or dizziness
- headache
- fatigue
- aching, tender or weak muscles not caused by exercise
- persistent dry cough
- indigestion
- taste disturbance

- mild stomach upsets such as feeling sick, diarrhoea or stomach pain.

These side effects are usually mild but may be serious.

Tell your doctor immediately if you notice any of the following:

- fast or irregular heart beats
- itchy skin rash or other skin problems
- signs of frequent or worrying infections such as fever, mouth or tongue ulcers
- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly 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 DOLAPRIL and either tell your doctor immediately or go to Accident and Emergency at the nearest hospital:

- fainting within a couple of hours of taking DOLAPRIL
- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- severe dizziness and confusion with visual disturbances and speech problems
- chest pain or feeling of tightness, pressure or heaviness in the chest
- rapid, shallow breathing, cold clammy skin, a rapid, weak pulse, dizziness, weakness and fainting.

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 also occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After using DOLAPRIL

Storage

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

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

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

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

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 DOLAPRIL or the capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

DOLAPRIL comes in 4 strengths of capsules:

- DOLAPRIL 0.5 - white opaque capsule marked 'TN' over '5' in black ink
- DOLAPRIL 1 – scarlet and peach opaque capsule marked 'TN' over '1' in black ink
- DOLAPRIL 2 - scarlet opaque capsule marked 'TN' over '2' in black ink
- DOLAPRIL 4 - white opaque capsule marked 'TN' over '4' in black ink.

Each blister pack contains 28 capsules.

Ingredients

The active ingredient in DOLAPRIL is trandolapril.

- each DOLAPRIL 0.5 capsule contains 0.5 mg of trandolapril
- each DOLAPRIL 1 capsule contains 1 mg of trandolapril
- each DOLAPRIL 2 capsule contains 2 mg of trandolapril

- each DOLAPRIL 4 capsule contains 4 mg of trandolapril

The capsules also contain:

- lactose
- povidone
- maize starch
- croscarmellose sodium
- sodium stearyl fumarate.

The capsule shells contain:

- titanium dioxide (171)
- gelatin
- black printing ink
- brilliant blue FCF C142090 (133; 1 mg and 2 mg only)
- erythrosine C145430 (127; 1 mg and 2 mg only)
- allura red AC C116035 (129; 1 mg and 2 mg only)
- sunset yellow FCF C115985 (110; 1 mg only).

The capsules do not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

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Australian registration numbers

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DOLAPRIL 1 AUST R 125433
DOLAPRIL 2 AUST R 125434
DOLAPRIL 4 AUST R 125435

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