

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.

Talk to your doctor or pharmacist if you have any concerns about taking this medicine.

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 heart conditions.

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. You may feel fine and have no symptoms, but eventually hypertension can lead to serious health problems, including stroke, heart disease and kidney failure. DOLAPRIL helps to lower your blood pressure.

DOLAPRIL belongs to a group of medicines called Angiotensin Converting Enzyme (ACE) inhibitors. It works by relaxing your blood vessels, making it easier for blood to move around your body. This helps lower blood pressure and increase the supply of blood and oxygen to the heart.

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.

DOLAPRIL is not recommended for use in children as there have been no studies of its effects in children.

Before you take DOLAPRIL

When you must not take it

Do not take DOLAPRIL if you:

- Are allergic (sensitive) to trandolapril or any of the ingredients in DOLAPRIL capsules 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, tongue, throat, hands or feet.
- Have ever had an allergic reaction to any other ACE inhibitor. If you have had an allergic reaction to an ACE inhibitor before, you may be allergic to DOLAPRIL.
- You have a history of swelling of the face, lips, mouth, tongue, throat, hands or feet for no apparent reason. Taking DOLAPRIL could cause this problem to happen again.

- Are pregnant or planning to become pregnant. DOLAPRIL may affect your developing baby if you take it during pregnancy.
- Are breastfeeding or planning to breastfeed. Like most ACE inhibitors, DOLAPRIL is not recommended while you are breastfeeding.
- Are suffering from any obstruction that slows the flow of blood to the heart, such as narrowing of one of the valves in the heart (aortic stenosis).
- Recently had severe or prolonged sickness or diarrhoea.
- Have ever had the condition known as angioedema (a severe allergic skin condition).
- Are undergoing haemodialysis or having your blood treated outside your body. Taking DOLAPRIL could cause an allergic reaction.
- Are taking any of the following medications, or medications containing these ingredients:
 - aliskiren (under certain conditions)
 - neutral endopeptidase (NEP) inhibitors such as sacubitril and racecadotril.
 - Sacubitril in combination with Valsartan

DOLAPRIL must not be given 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 or if the capsules don't look quite right.

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, Sulfites which are present in the DOLAPRIL capsule shell.

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 conditions
- low blood pressure, which you may notice as dizziness or light-headedness
- high levels of potassium in your blood
- dizzy spells
- diabetes
- connective tissue disease
- are about to have surgery or a general anaesthetic.

In patients of African descent, ACE inhibitors are less effective in lowering blood pressure than in Caucasian patients.

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 e.g. to insect stings.

Tell your doctor if you have an intolerance to any sugars.

Dolapril contains sugars (as lactose)

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
- aliskiren
- neutral endopeptidase (NEP) inhibitors such as sacubitril or racecadotril
- diuretics, also known as fluid or water tablets
- anti-inflammatory pain medicines used to treat arthritis, pain or fever
- potassium supplements, large amounts of salt or potassium-containing salt substitutes in your food (check the label)
- any other medication associated with increases in potassium (e.g. trimethoprim/sulfamethoxazole - an antibiotic)
- any antidiabetic medicine including insulin or vildagliptin (used to lower blood glucose)
- lithium or tricyclic antidepressants (used to treat mood changes)
- sympathomimetics - these may be found in some decongestants, cough / cold remedies and asthma medicines
- antacids, used to treat heartburn and reflux
- immunosuppressants such as ciclosporin (medicines which lower the body's resistance to disease and treat or prevent organ transplant rejection)
- procainamide (used for abnormal heart rhythms)
- allopurinol (medicines used to treat gout)
- cytostatic medicines (medicines used to treat certain cancers)
- neuroleptic medicines (medicines used to treat certain mental and emotional conditions)
- general anaesthetics
- injectable gold (sodium aurothiomalate) (medicine used to treat rheumatoid arthritis).
- Heparin (used to thin the blood).

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.

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

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 have trouble remembering to take your medicine, as 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 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

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

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

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

Tell your doctor if you have excessive vomiting and/or diarrhoea while taking DOLAPRIL.

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

Drink plenty of water when you are using DOLAPRIL, especially if you sweat a lot (e.g. during hot weather or exercise).

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.

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 medicines, tell your doctor, dentist or pharmacist that you are taking DOLAPRIL.

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

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.

Go to your doctor regularly for a check-up.

Your doctor may occasionally do a blood test to check your potassium level in the blood and to 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
- nausea, vomiting, diarrhoea or stomach pains
- indigestion
- persistent dry cough
- headache
- unusual tiredness or weakness
- aching, tender or weak muscles not caused by exercise
- taste disturbance

These are the more common side effects of DOLAPRIL.

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

- fast or irregular heartbeat, also called palpitations
- signs of worrying or frequent infections such as fever, severe chills, sore throat or mouth ulcers
- itchy skin rash or other skin problems
- 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
- 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 monohydrate
- povidone
- maize starch
- croscarmellose sodium
- sodium stearyl-fumarate.

The capsule shells contain:

- titanium dioxide (171)
- gelatin
- black printing ink
- brilliant blue FCF CI42090 (133; 1 mg and 2 mg only)
- erythrosine CI45430 (127; 1 mg and 2 mg only)
- allura red AC CI16035 (129; 1 mg and 2 mg only)
- sunset yellow FCF CI15985 (110; 1 mg only).

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

Sponsor

Arrow Pharma Pty Ltd
15-17 Chapel St
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Australia

Australian registration numbers

DOLAPRIL 0.5 AUST R 125432

DOLAPRIL 1 AUST R 125433

DOLAPRIL 2 AUST R 125434

DOLAPRIL 4 AUST R 125435

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