

GOPTEN

trandolapril

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Gopten.

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 Gopten 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 GOPTEN is used for

Gopten is used to treat high blood pressure (hypertension) and also to treat 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. Gopten helps to lower your blood pressure.

Gopten 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 prescribe Gopten for another reason. Ask your doctor if you have any questions about why Gopten has been prescribed for you.

Gopten is only available with a doctor's prescription.

Gopten is not addictive.

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

Before you take GOPTEN

When you must not take it

Do not take Gopten if you:

- Are allergic (sensitive) to trandolapril or any of the ingredients in Gopten 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 Gopten.
- You have a history of swelling of the face, lips, mouth, tongue, throat, hands or feet for no apparent reason.

Taking Gopten could cause this problem to happen again.

- Are pregnant or planning to become pregnant
 - Gopten may affect your developing baby if you take it during pregnancy
 - Are breastfeeding or planning to breastfeed
 - Like most ACE inhibitors, Gopten 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 Gopten 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
- Gopten must not be given to children.
- Do not take Gopten after the expiry date (EXP) printed on the pack.

Do not take Gopten 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 Gopten, contact your doctor.

Before you start to take it

Tell your doctor if you have allergies to:

- sulfites which are present in the Gopten capsule shell
- 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 or liver problems
- regular dialysis, blood filtration or similar procedures
- high levels of potassium in your blood
- dizzy spells
- diabetes
- connective tissue disease
- are about to have surgery or a general anaesthetic
- any heart conditions

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 excessive swelling of the face, lips, mouth, tongue or throat.

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

Tell your doctor if you are about to receive desensitisation treatment for an allergy e.g. to insect stings

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

Gopten should not be used during pregnancy or while you are breast-feeding.

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

Gopten contains sugars (as lactose).

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

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 Gopten may interfere with each other.

These include:

- any other medication for high blood pressure
- aliskiren
- neutral endopeptidase (NEP) inhibitors such as sacubitril or racecadotril
- diuretics (also known as 'fluid' tablets)
- potassium supplements or large amounts of salt
- potassium - containing salt substitutes in your food (check the label)
- any other medication associated with increases in potassium (e.g. trimethoprim/sulfamethoxazole - an antibiotic)
- anti-inflammatory pain medicines used to treat arthritis, pain or fever
- 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
- **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 Gopten or may affect how well it works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also have a more complete list of medicines to be careful of or to avoid while taking Gopten.

How to take GOPTEN

How much to take

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

The usual dosage is one or two capsules taken once daily, up to a maximum of 4mg (two 2mg capsules) once daily.

Dosage for older people over 65 years.

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

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

These directions may differ from the information contained in this leaflet.

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

How to take it

Swallow Gopten with water.

When to take it

Take Gopten at about the same time each day.

Taking your capsules at 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 Gopten 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 Gopten.

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.

How long to take it

Gopten helps control your condition, but does not cure it.

Therefore you must take Gopten every day. Continue taking the capsules for as long as your doctor tells you.

If you take too much (overdose)

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (Australia

telephone 13 11 26 or New Zealand 0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Gopten. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are using GOPTEN

Things you must do

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

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

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

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

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

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

If you do not drink enough water while taking Gopten, 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 Gopten.

If you are about to be started on any new medicines, tell your

doctor, dentist or pharmacist that you are taking Gopten.

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

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

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

Do not take Gopten to treat any other complaints unless your doctor tells you to.

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

Things to be careful of

If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up.

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. If this problem continues or gets worse, talk to your doctor.

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

Gopten may cause dizziness, light-headedness or tiredness in some people. Make sure you know how you react to Gopten 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.

Side effects

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

Gopten 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.

Tell your doctor 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 Gopten.

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

- fast or irregular heart beat, 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 urgent medical

attention. Serious side effects are rare.

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

- fainting within a couple of hours of taking Gopten
- swelling of the face, lips, mouth, tongue 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. Ask your doctor or pharmacist for more information about side effects, as they have a more complete list of side effects. Inform your doctor promptly about these or any other symptoms. If the condition persists or worsens, seek medical attention.

Do not be alarmed by this list of possible side effects. You may not experience any of them or only some of them.

Tell your doctor if you notice anything 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 GOPTEN

Storage

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

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

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

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

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

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 Gopten 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

Gopten capsules are available in four different strengths. Each strength has a separate colour to distinguish it from the others.

- Gopten 0.5mg: red & yellow capsules
- Gopten 1mg: red & orange capsules
- Gopten 2mg: red capsules
- Gopten 4mg: red and maroon capsules

All strengths are available in packs of 28 capsules

Ingredients

Active Ingredient:

- Gopten 0.5mg - 0.5 mg trandolapril per capsule
- Gopten 1mg - 1mg trandolapril per capsule

- Gopten 2mg - 2mg trandolapril per capsule
- Gopten 4mg - 4mg trandolapril per capsule

Inactive Ingredients:

- maize starch
- lactose monohydrate
- povidone
- sodium stearyl fumarate
- gelatin
- titanium dioxide
- sodium lauryl sulfate
- erythrosine
- iron oxide yellow

The 4 mg strength capsule also contains:

- iron oxide black

Gopten contains sugars (as lactose) and sulfites.

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

Supplier

Gopten is supplied in Australia by:

Mylan Health Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point, NSW 2000

www.mylan.com.au

Phone: 1800 314 527

Gopten Australian Registration

Numbers:

0.5mg capsules:

AUST R 45456

1.0mg capsules:

AUST R 45455

2.0mg capsules:

AUST R 45457

4.0mg capsules:

AUST R 96969

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