GOPTEN®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking GOPTEN?

GOPTEN contains the active ingredient trandolapril. GOPTEN is used to treat high blood pressure (hypertension) and also to treat some heart conditions. For more information, see Section 1. Why am I taking GOPTEN? in the full CMI.

2. What should I know before I take GOPTEN?

Do not take if you have ever had an allergic reaction to trandolapril (or any other ACE inhibitor), or any of the ingredients listed at the end of the CMI.
Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section 2. What should I know before I use GOPTEN? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with GOPTEN and affect how it works.
A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take GOPTEN?

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

More instructions can be found in Section 4. How do I take GOPTEN? in the full CMI.

5. What should I know while taking GOPTEN?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking trandolapril. • 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.
Things you should 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.
Driving or using machines	• 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.
Drinking alcohol	• If you drink alcohol, dizziness or light-headedness may be worse.
Looking after your medicine	• Keep your capsules in a cool dry place where the temperature stays below 25°C.

For more information, see Section 5. What should I know while taking GOPTEN? in the full CMI.

6. Are there any side effects?

Tell your doctor if the following worry you: dizziness, nausea, vomiting, diarrhoea, indigestion, persistent dry cough, headache, unusual tiredness, aching, tender or weak muscles and taste disturbance.
Tell your doctor immediately if you notice any palpitations, signs of infection or skin problems.
Stop taking GOPTEN and tell your doctor immediately or go to your nearest hospital if the following happen; fainting, swelling of face, lips, mouth, tongue or throat, severe dizziness, chest pain, rapid, shallow breathing, cold clammy skin or a rapid, weak pulse.
For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

GOPTEN®

Active ingredient(s): *trandolapril*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking GOPTEN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using GOPTEN.**

Where to find information in this leaflet:

1. Why am I taking GOPTEN?
2. What should I know before I take GOPTEN?
3. What if I am taking other medicines?
4. How do I take GOPTEN?
5. What should I know while taking GOPTEN?
6. Are there any side effects?
7. Product details

1. Why am I taking GOPTEN?

GOPTEN contains the active ingredient trandolapril. 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.

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.

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 not addictive.

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

2. What should I know before I take GOPTEN?

Warnings

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.

- you 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.

- you 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)
- you recently had severe or prolonged sickness or diarrhoea
- you have ever had the condition known as angioedema (a severe allergic skin condition)
- you are undergoing haemodialysis or having your blood treated outside your body.

  Taking GOPTEN could cause an allergic reaction.

- you 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 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.

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 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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

GOPTEN may affect your developing baby if you take it during pregnancy

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Like most ACE inhibitors, GOPTEN is not recommended while you are breastfeeding.

3. What if I am taking other medicines?

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

Some medicines may interfere with GOPTEN and affect how it works.

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect GOPTEN.

4. How do I 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 4 mg (two 2 mg 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

Swallow GOPTEN with water.

When to take GOPTEN

- 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.
- 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 forget to take GOPTEN

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.

If you take too much GOPTEN

If you think that you have taken too much GOPTEN, you may need urgent medical attention.

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

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking GOPTEN?

Things you should 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 taking 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 should 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.

- If this occurs, do not drive.
- If you drink alcohol, dizziness or light-headedness may be worse.Some medicines may require additional subheading(s) relevant to monitoring the condition and actions to be taken while on the medicine e.g. bleeding risk with antiplatelets / hypoglycaemia and what to do.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol, dizziness or light-headedness may be worse.

If this occurs, do not drive.

Looking after your medicine

- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking GOPTEN or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any 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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• light-headedness, dizziness or vertigo • nausea, vomiting, diarrhoea or stomach pains/stomach upset • constipation • persistent dry cough • headache • unusual tiredness or weakness • aching, tender or weak muscles not caused by exercise • taste disturbance • excessive sweating	**Tell your doctor if you notice any of these and they worry you.** These are the more common side effects of GOPTEN.

Serious side effects

Serious side effects	What to do
• slow heartbeat, fast or irregular heart beat (also called palpitations) • signs of worrying or frequent infections such as fever, severe chills, sore throat or mouth ulcers	**Tell your doctor immediately if you notice any of these.** These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.
• itchy skin rash or other skin problems • fever, upper stomach pain, feeling generally unwell • symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal.	
• 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	**If any of the following happen, stop taking GOPTEN and tell your doctor immediately or go to Accident and Emergency at your nearest hospital.** 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.

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What GOPTEN contains

Active ingredient (main ingredient)	• GOPTEN 0.5 mg - 0.5 mg trandolapril per capsule • GOPTEN 1 mg - 1mg trandolapril per capsule • GOPTEN 2 mg - 2mg trandolapril per capsule • GOPTEN 4 mg - 4mg trandolapril per capsule
Other ingredients (inactive ingredients)	• maize starch • lactose monohydrate • povidone • sodium stearylfumarate • gelatin • titanium dioxide • sodium lauryl sulfate • erythrosine • iron oxide yellow The 4 mg strength capsule also contains: • iron oxide black
Potential allergens	GOPTEN contains sugars as lactose and sulfites.

Do not take this medicine if you are allergic to any of these ingredients.

What GOPTEN looks like

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

GOPTEN 0.5 mg: White to off white granules filled in Size 4 hard gelatin capsules with yellow opaque cap and red opaque body. (AUST R 45456)

GOPTEN 1 mg: White to off white granules filled in Size 4 hard gelatin capsules with orange opaque cap and red opaque body. (AUST R 45455)

GOPTEN 2 mg: White to off white granules filled in Size 4 hard gelatin capsules with red opaque cap and red opaque body. (AUST R 45457)

GOPTEN 4 mg: White to off white granules filled in Size 2 hard gelatin capsules with maroon opaque cap and red opaque body. (AUST R 96969)

All strengths are available in blister packs of 28 capsules.

Who distributes GOPTEN

Viatris Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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