

PACKAGE LEAFLET: INFORMATION FOR THE USER

Gopten

0.5mg and 2mg Capsules

TRANDOLAPRIL

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What Gopten Capsules are and what they are used for
2. What you need to know before you take Gopten Capsules
3. How to take Gopten Capsules
4. Possible side effects
5. How to store Gopten Capsules

1. WHAT GOPTEN CAPSULES ARE AND WHAT THEY ARE USED FOR

Trandolapril belongs to a group of medicines called angiotensin-converting enzyme inhibitors (sometimes called ACE inhibitors). These work by widening blood vessels which makes it easier for the heart to pump blood around the body. This helps to lower blood pressure.

Gopten Capsules are used to treat hypertension (high blood pressure). The capsules may also be prescribed to protect your heart after a heart attack.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE GOPTEN CAPSULES

Do not take Gopten Capsules:

- If you are allergic to trandolapril
- If you are allergic to any of the other ingredients in this medicine
- If you are allergic to other ACE inhibitors
- If you are more than 3 months pregnant.(It is also better to avoid Gopten Capsules in early pregnancy – see pregnancy section)
- If you or someone in your family has had symptoms such as swelling of the face, tongue or throat, intense itching, skin rashes, difficulty in swallowing and/or breathing associated with previous ACE

inhibitor treatment or have had these symptoms in any other circumstances (this is a condition called 'angioedema').

If you are unsure, talk to your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking Gopten Capsules.

- If you have heart problems or if you have any kidney or liver disease. Your doctor may need to monitor you and change the dose of your medicine
- If you suffer from a kidney disorder caused by the narrowing of the artery in the kidney
- If you have been taking diuretics (water tablets) for a long time, have a restricted salt diet or are undergoing dialysis
- If you have recently had severe or prolonged sickness (vomiting) or diarrhoea
- If you are undergoing haemodialysis. Tell your doctor this so that a different technique can be chosen to prevent allergic reactions
- If you have a condition known as aortic stenosis (the narrowing of one of the valves in the heart) or any other obstruction that slows the flow of blood in the heart
- If you have a condition known as primary hyperaldosteronism
- If you are undergoing desensitisation treatment for an insect's sting (a bee or wasp's sting)
- If you have diabetes
- If you are undergoing blood/plasma exchange treatment for a high lipid problem
- If you need an operation or an anaesthetic. Tell your doctor or dentist that you are taking trandolapril
- If you have a collagen vascular disease such as scleroderma or systemic lupus erythematosus. Tell your doctor immediately if you develop any sort of infection while taking trandolapril.

You must tell your doctor if you think you are (or might become) pregnant. Gopten Capsules are not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

It is important that you tell your doctor everything about your condition and of any problems that you may have had in the past. Tell him if you have ever reacted badly to Gopten Capsules.

Your doctor may check your kidney function before you start to take Gopten Capsules and may need to repeat this test whilst you are taking them.

Gopten Capsules are not recommended for children.

Other medicines and Gopten Capsules

Tell your doctor if you are already taking any of the following as they may interact with your medicine:

- Diuretics (water tablets) including potassium sparing diuretics such as amiloride
- Allopurinol (a treatment for gout) or procainamide (used to correct irregular heartbeats)
- Immunosuppressants used for the treatment of auto-immune disease (e.g. rheumatoid arthritis) or following transplant surgery
- Lithium (an antidepressant)
- Medicines for the treatment of high blood pressure including vasodilators
- Medicines for the treatment of diabetes such as insulin and sulphonylurea tablets
- Medicines or supplements containing potassium
- Non-steroidal anti-inflammatory drugs (NSAIDs) including aspirin
- Medicines for the treatment of depression or schizophrenia
- Medicines used for the treatment of low blood pressure, shock, colds and asthma (e.g. (pseudo)ephedrine and (nor)adrenaline).
- Heparin (used to thin the blood)
- Antacids (used to treat indigestion and /or heartburn)

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Gopten Capsules with food, drink and alcohol

It is recommended that you do not drink alcohol whilst taking Gopten Capsules.

Pregnancy and breast-feeding

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Gopten Capsules before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Gopten Capsules. Gopten Capsules are not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breastfeeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Gopten Capsules are not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Gopten Capsules can make some people feel dizzy or faint, especially when they first start to take the capsules. This can be made worse by alcohol, even in small amounts.

Do not drive, operate machinery or do anything that requires you to be alert for several hours after your first dose or any increase in the dose of Gopten Capsules. Wait and see how the capsules affect you.

If you are unsure about anything you should discuss it with your doctor or pharmacist.

Important information about some of the ingredients of Gopten Capsules

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE GOPTEN CAPSULES

Always take Gopten Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Swallow your capsules whole with a little water without chewing them. Gopten Capsules can be taken before, during or after your meal but it is recommended that you take your capsules at the same time each day.

The number of capsules that you will need to take will depend on what you are being treated for. If you are already taking a diuretic medicine ("water tablets") your doctor may tell you to reduce the dose of the diuretic or even to stop taking it before you start to take Gopten Capsules. Always follow your doctor's advice carefully.

For hypertension (high blood pressure)

The recommended starting dose is one 0.5mg capsule once a day. The usual maintenance dose is one 1mg or 2mg capsule once a day. The maximum dose of Gopten Capsules is 4mg a day.

Following a heart attack

The recommended starting dose is 0.5mg once a day which will be given 3-7 days after the heart attack. The dose will then be increased to 1mg the next day and gradually increased further up to a maximum of 4mg each day.

Patients with kidney problems

If you suffer from minor kidney problems, your doctor will normally prescribe the usual dose. However if you suffer from more serious kidney problems the maximum dose of Gopten Capsules is 0.5-1mg once a day depending on severity of problem.

Patients with liver problems

If you have liver problems, the maximum dose of Gopten Capsules is one 2mg capsule once a day.

If you take more Gopten Capsules than you should, you may cough a lot and/or feel dizzy, anxious or faint. Your heart may also flutter or beat faster or slower than normal and you may experience heavy or rapid breathing. You should contact a doctor immediately or go to the nearest hospital casualty department. Remember to take the pack and any remaining capsules with you.

If you forget to take your Gopten Capsules at the right time, take them as soon as you remember. However if it is almost time for your next dose do not take the missed dose at all. Never take a double dose to make up for a forgotten or missed dose.

If you stop taking Gopten Capsules, your original symptoms may return. It is important that you keep taking these capsules until your doctor tells you to stop. Don't stop just because you feel better. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you notice a rash, blistering or other effects on the skin, eyes, mouth or genitals, itching or high temperature, you should stop taking Gopten Capsules and contact your doctor immediately.

Tell your doctor immediately if:

- You get a swollen face, tongue and/or throat, severe reddening of the skin (hives) and/or have difficulty in swallowing and/or breathing (angioedema)
- You feel ill after your first dose (a few people react to their first dose and feel very dizzy, weak, faint and are sick)
- You get a lot of infections with sore throats or mouth ulcers or if you bruise more easily while you are on this medicine.

The following side effects have been reported:

Common (may affect up to 1 in 10 people):

- dizziness/ light-headedness
- headache
- diarrhoea
- vomiting
- cough
- fainting when standing up
- kidney problems
- weakness or loss of strength (asthenia)

Uncommon (may affect up to 1 in 100 people):

- mood changes
- numb or tingling hands and feet
- dizziness/spinning feeling
- change in sense of taste
- sleeping problems
- heart problems such as chest pain, heart attack, angina, heart disorder, irregular or fast heart beat
- upper respiratory tract infection
- runny or stuffy nose
- shortness of breath
- inflamed sinuses
- sore throat, hoarseness
- Raynaud's phenomenon (fingers and toes appear white or bluish and cold or numb)
- feeling sick (nausea)
- indigestion and stomach pain

- constipation
- anorexia
- rash, itching
- impotence
- fatigue
- feeling of weakness (malaise)
- chest pain
- swelling
- feeling abnormal
- increases in potassium, creatinine or urea in the blood
- increases in liver enzymes
- inflammation of the tongue and mouth
- disturbed sleep patterns (insomnia)
- reduced sex drive or erectile dysfunction
- stroke
- back pain, muscle spasms, pain in hands and feet

Rare (may affect up to 1 in 1,000 people):

- dry mouth
- difficulty in breathing or wheezing
- serious allergic reactions causing swelling of the face, fingers/toes, tongue or throat
- lumpy rash with itching
- hives (urticarial)
- loss of appetite
- hair loss
- psoriasis, eczema, acne, dry skin, skin rash (erythema multiforme)
- problems with balance
- blurred vision
- muscle twitching
- nervousness
- kidney failure
- toxic substances in the blood due to kidney problems
- urinary tract infection
- increase in the frequency and amount of urination
- hot flushes
- blushing
- ringing in the ears
- abnormal enlargement of breasts in men
- changes in blood: low blood cell count, low haemoglobin, low sodium, high bilirubin
- increase in protein levels in urine
- anaemia (pale skin, weakness or breathlessness due to low red blood cell count)
- loosening of the nails
- sensitivity to light
- increased risk of bleeding or bruising due to low blood platelets
- increased risk of infection due to low white blood cell count
- bone marrow depression leading to low blood cells production
- increased numbers of white blood cells
- excessive sweating
- hypersensitivity
- increased levels of glucose, lipids, cholesterol and uric acid in your blood
- gout
- increased appetite
- enzyme abnormality

- seeing and hearing things which are not there (hallucinations), anxiety, agitation, apathy, mental confusion, depression
- sleepiness (somnolence)
- migraine with or without aura
- swelling of the eyelids and eyes, blurred vision, eye disorder
- extremely sore throat (pharyngitis)
- high blood pressure
- disease of the blood vessels (angiopathy), narrowing of the blood vessels, varicose veins
- nosebleed
- vomiting blood (hematemesis)
- inflammation of the stomach lining (gastritis), wind (flatulence)
- pain in the bones and joints (including osteoarthritis)
- congenital arterial malformation
- ichthyosis (hereditary dry skin)
- injury

Very rare (may affect up to 1 in 10,000 people):

- low blood sugar levels
- inflammation in the lungs
- inflamed pancreas
- jaundice
- hepatitis (inflamed liver)
- abdominal pain with or without nausea and vomiting
- autoimmune disease such as pemphigus (in which the body is attacked by its own immune system)
- swollen glands
- low or no urine production
- serious illnesses with blistering of the skin (toxic epidermal necrosis) or skin, mouth, eyes and genitals (Stevens-Johnson syndrome)
- bacterial infection in the kidneys

Not known (frequency cannot be estimated from the available data):

- decrease in the number of all blood cells (pancytopenia)
- fever
- heart rhythm disorder (atrioventricular block), loss of heart function (cardiac arrest), abnormal heart rhythm, disruption in the electrical signals of the heart
- muscle pain
- abnormal results of blood tests or other medical examinations

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE GOPTEN CAPSULES

Keep this medicine out of the sight and reach of children.

Do not use Gopten Capsules after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

This leaflet was last revised in December 2013.