

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT
Trandolapril 0.5 mg, 1 mg, 2 mg and 4 mg Capsules, hard

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. See section 4.

What is in this leaflet:

1. What Trandolapril is and what it is used for
2. What you need to know before you use Trandolapril
3. How to take Trandolapril
4. Possible side effects
5. How to store Trandolapril
6. Contents of the pack and other information

1. What Trandolapril is and what it is used for

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

Trandolapril is used to treat high blood pressure. It may also be used to help protect the heart after a heart attack.

2. What you need to know before you take Trandolapril

Do not take Trandolapril if:

- you are allergic to trandolapril, other ACE inhibitors (e.g. perindopril or ramipril) or any of the other ingredients of this medicine (listed in section 6)
- you have had the condition known as angioedema (swelling of the hands, face, lips, tongue or throat with difficulty swallowing or breathing, possibly together with an itchy rash such as nettle rash or hives) or Quincke's oedema (this is a severe allergic skin condition after taking an ACE inhibitor)
- you, or a member of your family, have a history of suffering from angioedema
- you are more than 3 months pregnant. (It is also better to avoid Trandolapril in early pregnancy – see pregnancy section.)
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- if you have taken or are currently taking sacubitril/valsartan, a medicine used to treat a long term (chronic) heart failure in adults, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased.

Warnings and precautions

Talk to your doctor or pharmacist before taking Trandolapril if:

- you have recently started or been taking diuretics (water tablets) for a long time, or are on a low salt diet
- have or have had severe or prolonged vomiting or diarrhoea

- you have been told that you have a narrowing of the blood vessels to one or both of your kidneys (renal stenosis)
- you have a narrowing of one of the valves in the heart (aorta stenosis) or in the outflow from the left chamber of the heart. You should not take Trandolapril. Your doctor will change your medication to something more appropriate for you.
- you suffer from a condition known as collagen vascular disease (this is sometimes called connective tissue disease, for example lupus or scleroderma). You are more likely to experience changes to your blood that can cause you to develop an infection
- you are Afro-Caribbean. Trandolapril may be less effective at lowering your blood pressure or trandolapril may increase the risk of angioedema
- you suffer from diabetes mellitus. Trandolapril could cause your blood glucose levels to decrease too much.
- you suffer from heart failure or cirrhosis of the liver with swelling that can also be around your stomach. You are more likely to suffer from a very large drop in your blood pressure (hypotension) when you start to take the tablets which may make you feel faint or light-headed.
- you are on kidney dialysis as you may be at risk of serious allergic reactions (some kinds of dialysis membrane may not be suitable). You may need to be monitored more closely by your doctor.
- you are taking any of the following medicines, the risk of angioedema (rapid swelling under the skin in area such as the throat) is increased:
 - sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors (used to avoid rejection of transplanted organs).
 - neprilysin (NEP) inhibitors such as sacubitril (available as fixed-dose combination with valsartan), used in patients with heart failure, and racecadotril, used in patients with acute diarrhoea.
- you have other liver or kidney problems including if you have had a kidney transplant.
- you are over 70 years of age or have too much acid in the blood (metabolic acidosis). These can increase levels of potassium in your blood which can cause problems with your heart.
- you are being treated with medicine that lowers your immune response.
- you are to undergo LDL apheresis (which is removal of cholesterol from your blood by a machine).
- you are going to have desensitisation treatment to reduce the effects of an allergy to stings (such as bee or wasp).
- you are taking any of the following medicines used to treat high blood pressure:
 - an angiotensin II receptor blocker (ARBs) (also known as sartans - for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems.
 - aliskiren.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading 'Do not take Trandolapril if'

You must tell your doctor if you think you are (or might become) pregnant. Trandolapril is 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).

While taking Trandolapril

If you develop any of the following symptoms you should let your doctor know immediately:

- You feel dizzy or faint after your first dose. A few people react to their first dose or when their dose is increased by feeling dizzy, weak, faint or sick.
- Sudden swelling of the lips, tongue, face, throat or neck, possibly also hands and feet, wheezing or hoarseness. This condition is called angioedema. This may occur at any time during treatment.
- Stomach pain, possibly also feeling sick or being sick. This may be a symptom of angioedema in the stomach (intestinal angioedema).
- High temperature, sore throat or mouth ulcers (these may be symptoms of infection caused by the lowering of the number of white blood cells).

- Yellowing of the skin and whites of eyes (jaundice) or blood tests show an increase in liver enzymes. These may be signs of liver disease.
- A persistent cough.

If you need to have surgery or will be given an anaesthetic, tell your doctor, dentist or hospital staff that you are taking Trandolapril, because taking Trandolapril at this time could cause your blood pressure to drop further.

Your doctor may perform blood tests before your treatment begins and during your treatment to monitor your blood potassium levels and your kidney function

Other medicines and Trandolapril

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, herbal products or natural products. Remember to tell your doctor about Trandolapril if you receive another medication during your treatment or shortly after your treatment with Trandolapril. Your doctor may need to change your dose and/or to take other precautions. It is especially important to inform your doctor if you take:

- NEP inhibitors such as sacubitril (available as fixed-dose combination with valsartan) and racecadotril: the risk of angioedema (rapid swelling under the skin in areas such as the throat) may be increased.
- If you are taking any of the following medicines, the risk of angioedema may be increased:
 - Racecadotril, a medicine used to treat diarrhoea;
 - Medicines used to prevent organ transplant rejection and for cancer (e.g., temsirolimus, sirolimus, everolimus).
 - Vildagliptin, a medicine used to treat diabetes.
- Other medicines for high blood pressure as this may increase the effect of trandolapril.
- Potassium supplements (including salt substitutes), potassium-sparing diuretics (e.g. spironolactone, triamterene, or amiloride) and other medicines that can increase the amount of potassium in your blood (e.g. trimethoprim and co-trimoxazole for infections caused by bacteria; ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection; and heparin, a medicine used to thin blood to prevent clots).
- Anti-inflammatory pain killers (NSAIDs – e.g. ibuprofen, diclofenac, indometacin, acetylsalicylic acid and COX-2 inhibitors), as these may decrease the effect of trandolapril.
- Lithium, a medicine used to treat mental health conditions, as trandolapril may increase levels of this medicine in your body.
- Tricyclic antidepressants (e.g. amitriptyline, dosulepin) as these medicines can increase the effects of trandolapril.
- Medicines for diabetes (such as insulin, glibenclamide or gliclazide), Trandolapril could cause your blood glucose levels to decrease too much.
- Antacids, to relieve indigestion; do not take within 2 hours of trandolapril. This is because the antacids may stop your body absorbing the trandolapril effectively.
- Allopurinol (for gout) or procainamide (for abnormal heart rhythms), as these may increase the risk of developing low levels of white blood cells in your body.
- Immunosuppressants (e.g. ciclosporin) that lower the body's immune response, steroid medication (e.g. prednisolone, hydrocortisone) or anticancer medication (cytostatics), as these medications may increase the risk of developing low levels of white blood cells in your body.
- medicines containing ephedrine, noradrenaline (norepinephrine) or adrenaline (epinephrine), as these reduce the effect of trandolapril.
- medicines containing sodium aurothiomalate (gold) as these may increase the risk of side effects occurring.
- Opiates (strong pain killers) such as methadone, codeine and morphine as these may cause a drop in your blood pressure.
- Antipsychotic drugs such as chlorpromazine, thioridazine, flupentixol as these may cause a drop in your blood pressure.
- An angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings 'Do not use Trandolapril if' and 'Warnings and precautions')
- Medicines which are most often used to avoid rejection of transplanted organs (sirolimus,

everolimus and other medicines belonging to the class of mTOR inhibitors). See section “Warnings and precautions”.

Contact your doctor and inform them if you are taking any of the above medications. It may be necessary to adjust the dose.

Trandolapril with alcohol

Drinking alcohol increases the blood pressure lowering effect of Trandolapril.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Trandolapril before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Trandolapril. Trandolapril is 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.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Trandolapril is 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.

Driving and using machines

Trandolapril can make some people feel dizzy, faint or tired especially when they first start to take the capsules. 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. Wait and see how the capsules affect you.

Trandolapril contains lactose

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

[For 0.5 mg, 1 mg and 2 mg] contains sunset yellow (E110). This medicine may cause allergic reactions.

3. How to take Trandolapril

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Swallow your capsules whole without chewing them and take them with a glass of water. Always take them at the same time of day

The number of capsules that you will need to take will depend on what you are treated for. If you are already taking diuretics your doctor may tell you to reduce the dose of the diuretic or even tell you to stop taking them, before you start to take Trandolapril.

Adults:

High blood pressure (hypertension):

The recommended starting dose is 0.5 mg once a day. Your doctor will probably increase this dose to 1-2 mg daily. The maximum dose is 4 mg a day.

Patients with heart failure and high blood pressure:

The hospital will initiate your treatment. The recommended starting dose is 0.5 mg once a day.

Treatment following a heart attack:

Treatment will normally be started as early as the third day after a heart attack, usually at a low dose of 0.5 mg each day. Your doctor will probably increase this dose gradually to a maximum of 4 mg

each day.

Dose for adults treated earlier with diuretics (water tablets):

The diuretic treatment (water tablets) should be discontinued at least 72 hours (3 days) before beginning treatment with Trandolapril, and/or treatment may be started with 0.5 mg once daily. Afterwards the dose will be adjusted when your doctor sees the effect of the treatment.

Older people:

It is not necessary to reduce the dose if you have normal kidney function. Your doctor will watch your blood pressure and measure your kidney function during treatment.

However, caution is needed if at the same time you are being treated with diuretics (water tablets) or you have reduced heart, liver or kidney function.

Use in children and adolescents:

Trandolapril should not be given to children.

Patients with kidney problems:

Your doctor will adjust your dose depending on the results of your laboratory tests (0.5-1 mg daily). Patients undergoing kidney dialysis: 0.5 mg daily.

Patients with liver problems:

The initial dose is 0.5 mg daily. Afterwards your doctor may adjust your dose as needed.

If you take more Trandolapril than you should

Contact your doctor, hospital or pharmacy, if you have taken too much of this medicine.

The symptoms of overdose are severely reduced blood pressure, shock, slowing down of thought processes (lethargy), slow pulse, disturbances in the salt balance and reduced kidney function.

If you forget to take Trandolapril

Do not take a double dose to make up for a forgotten dose.

If you stop taking Trandolapril

It is important that you keep taking the capsules until your doctor tells you to stop. Do not stop just because you feel better. If you stop taking the capsules, your condition may get worse.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Trandolapril immediately if you get any of the following effects and go straight away to hospital or seek medical advice from your doctor:

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

- an increase in the number of infections you get such as fever, severe chills, sore throat or mouth ulcers (this may indicate you have a low number of white blood cells in your body)
- sudden collapse, numbness or weakness in the arms or legs, headache, dizziness and confusion, disturbances in vision, difficulty swallowing, slurred, mixed up or loss of speech (these may be signs of a stroke or mini stroke caused by a clot or bleed affecting blood supply to part of the brain)
- heavy or pressing sensation on your chest with chest pain and an increased shortness of breath on exercise (these may be signs of problems with your heart such as angina)

- sudden chest pain which may spread to the neck or arm, with a shortness of breath and a clammy feeling (these may be signs of a heart attack or other problems with your heart)
- an irregular heartbeat, fast or slow, which if fast, you may feel as a thumping in the chest (this may produce irregular activity when viewed on an ECG machine)
- a reduction in the working of the heart, which may cause tiredness, weakness and/or fluid retention such as swelling of the legs and ankles, difficulty breathing including coughing up frothy or watery phlegm
- vomiting blood (you may notice particles that look like coffee grounds)
- yellowing of your skin or whites of your eyes, dark urine, pale stools, tiredness, fever, nausea, weakness, drowsiness and abdominal pain, with test results showing abnormal liver function or high levels of bilirubin in the blood (these may be signs of problems with your liver or a blockage in your bile duct)
- sudden swelling of the lips, tongue, face, throat or neck which can lead to difficulty swallowing or breathing (these are signs of an allergic reaction)
- producing little or no urine, cloudy urine or blood in the urine, pain when passing urine or lower back pain (these may be signs of serious problems with your kidneys)
- birth defects including skin disorders and abnormal blood vessel formation
- tiredness, shortness of breath, coldness in your hands and feet and pale skin, difficulty in healing after a cut (this may indicate you have a low number of red blood cells in your body)

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

- Red-raised itchy skin swellings known as hives (signs of an allergic reaction)
- weakness, unexplained or abnormal bruising or bleeding or more frequent, potentially severe, infections (this may be signs of a severe reduction of all types of blood cells)
- persistent constipation with a swollen stomach and being sick (these may be signs of a blockage in your intestine)
- severe stomach pain which may radiate to your back (this may be signs of problems with your pancreas)
- a skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens-Johnson syndrome) or severe skin reactions which starts with painful red areas, then large blisters and ends with peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell (toxic epidermal necrolysis)

Other side effects include:

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

- dizziness or headache
- low blood pressure
- general weakness
- cough which may, or may not, produce phlegm

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

- difficulty sleeping
- a reduction in or lack of your sex drive
- drowsiness
- a spinning sensation with a loss of balance (can be known as vertigo)
- hot flushes
- shortness of breath, sore throat, cold or flu like symptoms (you may have an infection, congestion or inflammation of the airways)
- you may feel sick or have problems with your gut such as diarrhoea, constipation, stomach pain
- itching, skin rash

- back pain, muscle spasms or pain in your hands and feet
- difficulty maintaining an erection
- general feeling of being unwell or not quite your usual self
- chest pain
- fluid retention, swelling in your hands, feet or ankles
- a sensation of feeling the heart beating in the chest

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

- a feeling of light headedness or dizziness when standing up from a seated or lying down position (this may be due to a large drop in blood pressure)
- an uncomfortable or burning sensation or difficulty passing urine, an increase in the frequency of passing urine (you may have an infection in the kidneys, bladder or the tubes that connect them)
- an increase in the amount of urine you pass
- high levels of fat, such as cholesterol, in the blood (this may increase the risk of blood clots)
- blood tests may show high levels of glucose, uric acid or other nitrogen containing compounds, low levels of sodium or abnormal levels of enzymes
- an increase or decrease in appetite
- swollen, painful joints, especially in the toes due to a build-up of crystals (gout)
- nervousness, agitation, anxiety, depression, you may have a lack of interest or enthusiasm, or see, feel or hear things that aren't there
- fainting, muscle twitching, tingling the hands and feet
- migraines with or without aura, or a loss of taste.
- problems with your eyes and eyesight such as inflamed, swollen eyelids, watery eyes, blurred vision or double vision
- a constant ringing sound in the ears
- high blood pressure
- a decrease in temperature and colour to the hands and feet or varicose veins
- nosebleed, throat irritation or runny nose
- swelling of the stomach lining
- being sick, indigestion, dry mouth or passing wind
- excessive sweating
- silver scaly plaques on your skin (psoriasis) or inflamed, swollen, red, itchy, weeping or crusty skin (eczema)
- acne or dry skin
- muscle weakness or pain in your muscles, joints or bones. The joints may also be stiff and swollen
- tiredness
- injury
- blockage or damage of blood vessels, which can cause bleeding from the blood vessel, or in more serious cases, damage the surrounding tissue

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

- inflammation of the skin (dermatitis)

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

- increased levels of potassium in the blood
- problems with your balance
- increase of creatinine, urea, alkaline phosphatase, lactate dehydrogenase in the blood
- abnormal results from blood tests
- hair loss
- fever
- a decrease in the amount of oxygen-carrying protein in the blood (haemoglobin) and haematocrit (the proportion of space red blood cells take up in the blood)

Other side effects have been reported as a result of taking ACE inhibitors other than trandolapril. You may get these side effects. The frequency that these can occur cannot be estimated from the available data and include:

- swelling of the lining of the intestines (Intestinal angioedema)
- difficulty in knowing or remembering people, where you are or what the time is or problems with your memory
- difficulty breathing through the nose with pain in the face (these may be signs of sinus problems)
- swollen tongue
- an increase in the blood of certain white blood cells or an increase in markers in the blood which indicate the immune system may be attacking the body.
- measles spot like rash

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Trandolapril

- Keep this medicine out of the sight and reach of children.
- Store in the original package.
- Store below 25°C
- Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Trandolapril contains

- The active substance is trandolapril
- One capsule contains 0.5 mg, 1 mg, 2 mg or 4 mg trandolapril.
- The other ingredients are: lactose monohydrate (see section 2 ‘Trandolapril contains lactose’); pregelatinised maize starch; microcrystalline cellulose; dimeticone; magnesium stearate; colloidal anhydrous silica.
- The capsule shell contains gelatin; titanium dioxide (E171) and erythrosine (127). In addition, this strength also contains the following:

0.5 mg: sunset yellow (E110), (see section 2 ‘Trandolapril contains sunset yellow’), quinoline yellow (E104)

1 mg: sunset yellow (E110) (see section 2 ‘Trandolapril contains sunset yellow’)

2 mg: sunset yellow (E110) (see section 2 ‘Trandolapril contains sunset yellow’)

4 mg: red iron oxide (E172), black iron oxide (E172), yellow iron oxide (E172)

What Trandolapril looks like and contents of the pack

Each capsule contains a white to almost white powder

0.5 mg: light scarlet – rich yellow, oblong capsules

1 mg: light scarlet – light orange, oblong capsules

2 mg: light scarlet – light scarlet, oblong capsules

4 mg: swedish orange –light scarlet, oblong capsules

Contents:

0.5 mg, 1 mg, 2 mg and 4 mg:

14, 20, 28, 30, 50, 56, 84, 90 and 100 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, Herts. EN6 1TL

Manufacturer

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