

# Apo-Trandolapril Capsules

Contains the active ingredient, trandolapril

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## Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

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### What is in this leaflet

This leaflet answers some common questions about this medicine.

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 this medicine 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.

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### What trandolapril is used for

Trandolapril is used to treat high blood pressure, which doctors call 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. This medicine helps to lower your blood pressure.

Apo-Trandolapril Capsules 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 this medicine for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Apo-Trandolapril Capsules are only available with a doctor's prescription.

This medicine is not addictive.

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

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### Before you take trandolapril

#### *When you must not take it*

Do not take this medicine if you have had an allergic reaction to this medicine or to any of the ingredients 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.

Do not take this medicine if you have taken any other ACE inhibitor medicine before which caused your face, lips, tongue, throat, hands or feet to swell up or made it hard for you to breathe.

If you have had an allergic reaction to an ACE inhibitor before, you may be allergic to trandolapril.

Do not take this medicine if you have a history of swelling of the face, lips, mouth, tongue, throat, hands or feet for no apparent reason.

Taking this medicine could cause this problem to happen again.

Do not take this medicine if you are undergoing haemodialysis or having your blood treated outside your body.

Taking this medicine could cause an allergic reaction.

Do not take this medicine if you are pregnant or intend to become pregnant.

This medicine may affect your developing baby if you take it during pregnancy.

Do not take this medicine if you are breastfeeding or plan to breastfeed.

Like most ACE inhibitors, trandolapril is not recommended

while you are breastfeeding.

Do not take this medicine after the expiry date printed on the pack.

Do not take this medicine 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 this medicine, contact your doctor.

### **Before you start to take it**

Tell your doctor if you have allergies to:

- \* 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

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.

This medicine should not be used during pregnancy or while you are breastfeeding.

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

### **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 trandolapril may interfere with each other.

These include:

- \* other high blood pressure medicines including diuretics (fluid) tablets
- \* lithium - a medicine used to treat mood changes
- \* some medicines used to treat arthritis, pain or fever
- \* potassium supplements or large amounts of salt
- \* potassium-containing salt substitutes on your food (check the label)
- \* antacids
- \* medicines which lower the body's resistance to disease
- \* general anaesthetics

These medicines may be affected by trandolapril 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 with or avoid while taking this medicine.

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### **How to take this medicine**

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#### **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 this medicine, depending on how quickly your kidneys and liver can remove it from your body.

Follow all directions given to you by your doctor or 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 this medicine with water.

### **When to take it**

Take this medicine 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 this medicine 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 this medicine.

### **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**

This medicine helps control your condition, but does not cure it.

Therefore you must take this medicine 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 (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

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## **While you are taking trandolapril**

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### **Things you must do**

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

If you become pregnant while taking this medicine tell your doctor immediately.

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

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

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

Drink plenty of water when you are

using this medicine, especially if you sweat a lot (e.g. during hot weather or exercise).

If you do not drink enough water while taking this medicine, 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 this medicine.

If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist that you are taking this medicine.

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

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

This medicine 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 this medicine to anyone else, even if they have the same condition as you.

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

Do not stop taking this medicine, 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 this medicine affects you.

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

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## **Side effects of trandolapril**

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

This medicine 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 this medicine.

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 this medicine and tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

- \* fainting within a couple of hours of taking this medicine
- \* 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 occur in some patients. 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.

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## After taking this medicine

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### 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.

Store in a cool dry place below 25 degrees C.

Do not store this medicine 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 this medicine or the capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.

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## Product description

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### What trandolapril looks like

Apo-Trandolapril Capsules are available in four different strengths.

- \* Apo-Trandolapril Capsules 0.5 mg are orange coloured cap imprinted with 'TR' in black ink and ivory coloured body imprinted with '0.5' in black ink.
- \* Apo-Trandolapril Capsules 1 mg are orange coloured cap imprinted with 'TR' in black ink and light orange coloured body imprinted with '1' in black ink.

- \* Apo-Trandolapril Capsules 2 mg are orange coloured cap imprinted with 'TR' in black ink and orange coloured body imprinted with '2' in black ink.
- \* Apo-Trandolapril Capsules 4 mg are flesh coloured cap imprinted with 'TR' in black ink and flesh coloured body imprinted with '4' in black ink.

### Ingredients

Active Ingredients:

- \* Apo-Trandolapril Capsules 0.5 mg - 0.5 mg trandolapril per capsule
- \* Apo-Trandolapril Capsules 1 mg - 1 mg trandolapril per capsule
- \* Apo-Trandolapril Capsules 2 mg - 2 mg trandolapril per capsule
- \* Apo-Trandolapril Capsules 4 mg - 4 mg trandolapril per capsule

Inactive Ingredients:

- \* Lactose
- \* Starch- maize
- \* Povidone
- \* Sodium stearyl fumarate
- \* In addition the 0.5mg and 2mg capsule contains the following: gelatin, titanium dioxide (E171), erythrosine - FD & C red 3 (E127), yellow iron oxide (E172) and black ink (SW-9008).
- \* The 1 mg capsule contains: gelatin, titanium dioxide (E171), erythrosine - FD & C red 3 (E127), yellow iron oxide (E172), red iron oxide (E172) and black ink (SW-9008).
- \* The 4mg capsule contains: gelatin, titanium dioxide (E171), red iron oxide (E172) and black ink (SW-9008 / SW-9009).

This medicine does not contain gluten, sucrose, tartrazine or any other azo dyes

## **Australian Registration Numbers**

### **Apo-Trandolapril Capsules 0.5 mg capsules:**

AUST R: 135959

### **Apo-Trandolapril Capsules 1 mg capsules:**

AUST R: 135968

### **Apo-Trandolapril Capsules 2 mg capsules:**

AUST R: 135978

### **Apo-Trandolapril Capsules 4 mg capsules:**

AUST R: 135985

## **Sponsor**

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This leaflet was prepared in  
November 2007.