

Tranalpha

trandolapril

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TRANALPHA.

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 TRANALPHA 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 TRANALPHA is used for

TRANALPHA 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. TRANALPHA helps to lower your blood pressure.

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

TRANALPHA is only available with a doctor's prescription.

TRANALPHA is not addictive.

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

Before you take TRANALPHA

When you must not take it

Do not take TRANALPHA if you have an allergy to any medicine containing trandolapril or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- * shortness of breath
- * wheezing or difficulty breathing
- * swelling of the face, lips, tongue or other parts of the body
- * rash, itching or hives on the skin.

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 TRANALPHA.

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 TRANALPHA could cause this problem to happen again.

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

Taking TRANALPHA could cause an allergic reaction.

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

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

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

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

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- * 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.

TRANALPHA 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 TRANALPHA.

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 TRANALPHA may interfere with each other. These include:

- * other medicines used to treat high blood pressure 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 used to treat diabetes
- * medicines used to treat schizophrenia
- * some medicines used to treat depression
- * medicines which lower the body's resistance to disease
- * general anaesthetics.

These medicines may be affected by TRANALPHA or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take TRANALPHA

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 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 TRANALPHA, depending on how quickly your kidneys and liver can remove it from your body.

How to take it

Swallow the capsules with water.

When to take it

Take your 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 TRANALPHA 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 TRANALPHA.

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 for

Continue taking your medicine for as long as your doctor tells you.

This medicine helps control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much TRANALPHA. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are taking TRANALPHA

Things you must do

Have your blood pressure checked when your doctor says, to make sure TRANALPHA 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 TRANALPHA, 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 taking TRANALPHA, 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 TRANALPHA.

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.

TRANALPHA may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to check your potassium level in the blood and to see how your kidneys are working.

Things you must not do

Do not give TRANALPHA 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 your 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 TRANALPHA affects you.

This medicine may cause dizziness, light-headedness or tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

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 TRANALPHA.

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.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Tell your doctor or pharmacist 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 your medicine.

Tell your doctor as soon as possible 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.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

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

- * fainting within a couple of hours of taking TRANALPHA
- * swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- * swelling of the intestines which may cause nausea, vomiting, diarrhoea or severe stomach pain
- * 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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some people.

After taking TRANALPHA

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 degrees C.

Do not store TRANALPHA 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 expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

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

- * TRANALPHA 0.5 mg: red & yellow capsules
- * TRANALPHA 1 mg: red & orange capsules
- * TRANALPHA 2 mg: red capsules
- * TRANALPHA 4 mg: red & maroon capsules

Each blister pack contains 28 capsules.

Ingredients

Active Ingredient:

- * TRANALPHA 0.5mg - 0.5 mg trandolapril per capsule
- * TRANALPHA 1mg - 1mg trandolapril per capsule
- * TRANALPHA 2mg - 2mg trandolapril per capsule
- * TRANALPHA 4 mg - 4 mg trandolapril per capsule

Inactive Ingredients:

- * maize starch
- * lactose
- * povidone
- * sodium stearyl fumarate
- * gelatin
- * titanium dioxide (171)
- * sodium lauryl sulfate
- * erythrosine CI 45430 (127)
- * iron oxide yellow CI 77492 (172)

The 4 mg strength capsule also contains:

- * iron oxide black CI 77499

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

Supplier

TRANALPHA is supplied in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian Registration Numbers:

0.5 mg capsules: AUST R 130872

1 mg capsules: AUST R 130875

2 mg capsules: AUST R 130876

4 mg capsules: AUST R 130877

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