

APO-TELMISARTAN/ AMLODIPINE Tablets

Telmisartan/Amlodipine

Consumer Medicine Information

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

What is in this leaflet

This leaflet answers some common questions about telmisartan/amlodipine. 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 using 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 want to read it again.

What this medicine is used for

Telmisartan/amlodipine is used to lower high blood pressure (hypertension).

Telmisartan belongs to a group of medicines called angiotensin II receptor antagonists.

Amlodipine belongs to a group of medicines called calcium channel blockers.

How it works

Telmisartan and amlodipine work together to help stop your blood

vessels tightening. As a result, the blood vessels relax, and blood pressure is lowered.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

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

This medicine is not addictive.

There is not enough information to recommend the use of this medicine in children.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- telmisartan
- amlodipine
- dihydropyridine medicines
- 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, difficulty breathing or tightness in chest
- swelling of the face, lips, tongue, throat or other parts of the body

- rash, itching or hives on the skin

Do not take this medicine if you have or have had any of the following medical conditions:

- biliary obstruction
- severe liver problems
- heart attack
- diabetes or kidney problems and you are taking aliskiren (a medicine used to treat high blood pressure)

Do not take this medicine if you are pregnant, plan to become pregnant or are breastfeeding.

This medicine may affect your developing baby if you take it during pregnancy. It may also pass into human breast milk.

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, talk to 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:

- liver problems

- kidney problems or kidney transplant
- heart problems
- recent severe diarrhoea or vomiting
- primary aldosteronism or hyperaldosteronism
- diabetes
- high levels of potassium in your blood
- fructose or sorbitol intolerance

Tell your doctor if you are planning to have surgery, dental treatment or an anaesthetic.

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 or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and this one may interact with each other. These include:

- other medicines used to treat high blood pressure (e.g. ACE inhibitors, diuretics, aliskiren) especially if you have diabetes-related kidney problems
- potassium supplements or potassium-containing salt substitutes
- lithium, used to treat mood disorders
- non-steroidal anti-inflammatory drugs (NSAIDs) or COX-2 inhibitors, used to relieve pain and inflammation
- medicines used to treat epilepsy (e.g. carbamazepine, phenytoin, phenobarbital, primidone)
- some antibiotics (e.g. rifampicin)
- some antifungals, such as ketoconazole or itraconazole

- anti-proteases, medicines used to treat HIV infection such as ritonavir
- simvastatin, a cholesterol-lowering medication
- herbal medicines derived from St John's wort (*Hypericum perforatum*)
- grapefruit or grapefruit juice
- immunosuppressants such as cyclosporin or tacrolimus, medicines used to prevent organ rejection after transplantation.

These medicines may be affected by this medicine 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.

Other medicines not listed above may also interact with telmisartan/amlodipine.

How to take this medicine

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ to 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 much of this medicine you should take, depending on your condition and whether you are taking any other medicines.

How to take it

Swallow the tablet whole with a glass of water.

When to take it

Take this medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take it with or without food.

How long to take it

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

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the dose you missed and take your next dose at the usual time.

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 missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

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 of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using this medicine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

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

Tell your doctor you are going to have surgery or an anaesthetic or are going into hospital.

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

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

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 your medicine to treat any other complaint unless your doctor tells you to.

Do not stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how this medicine affects you.

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

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking telmisartan/amlodipine.

This medicine helps most people with hypertension, 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 attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- feeling light-headed, dizzy or faint
- headache
- an uncomfortable feeling in the stomach or belching after eating (indigestion)
- dry mouth
- diarrhoea
- feeling sick (nausea) or vomiting

The above list includes the more common side effects of your medicine.

Tell your doctor if you notice any of the following:

- swelling of hands, ankles or feet
- sleepiness or tiredness, weakness or difficulty sleeping
- tingling, numbness or pain in the hands or feet, pins and needles
- taste disturbances or loss of taste
- shaking or tremors
- slow heart beat
- palpitations

- low blood pressure
- flushed or pale skin
- cough
- stomach pain
- tender or enlarged gums
- itching, rash, redness of skin
- pain in joints
- muscle cramps
- aching, tender or weak muscles not caused by exercise
- back pain, pain in extremity
- night-time or frequent urination
- difficulty in getting or maintaining an erection
- generally feeling unwell
- chest pain
- feeling anxious or sad

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

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to Accident and Emergency at your nearest hospital:

- shortness of breath, wheezing, difficulty breathing or tightness in chest; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin (signs of an allergic reaction)

The above list includes very serious side effects and you may need urgent medical attention or hospitalisation.

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 patients.

Storage and Disposal

Storage

Keep your medicine in the pack until it is time to take it.

If you take your medicine out of its pack it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 30°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep this medicine 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 left over.

Product description

What it looks like

White and blue coloured, two-layered, modified capsule-shaped, biconvex uncoated tablets. White layer may contain blue specks and blue layer may contain white specks. "APO" engraved on one side.

- 40/5 mg: "40/5" on the other side. AUST R 276429.
- 40/10 mg: "40/10" on the other side. AUST R 276427.
- 80/5 mg: "80/5" on the other side. AUST R 276426.
- 80/10 mg: "80/10" on the other side. AUST R 276424. Available in blister pack of 28 tablets.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 40 mg or 80mg of telmisartan, and 5 mg or 10 mg of amlodipine as the active ingredient.

It also contains the following:

- isomalt
- mannitol

- povidone
- meglumine
- sodium hydroxide
- calcium hydrogen phosphate
- microcrystalline cellulose
- croscarmellose sodium
- silicon dioxide
- magnesium stearate
- brilliant blue FCF Aluminium Lake
- iron oxide yellow
- iron oxide black.

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

Sponsor

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