

APO-TELMISARTAN AMLODIPINE Tablets

Contains the active ingredient Telmisartan Amlodipine besylate

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about Telmisartan Amlodipine besylate. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- If there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Telmisartan Amlodipine tablets. It contains the active ingredients telmisartan and amlodipine besylate.

It is used to:

- lower high blood pressure (hypertension).

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.

How it works

Telmisartan and amlodipine help to reduce blood pressure in different ways:

- Telmisartan belongs to a group of medicines called angiotensin II receptor antagonists.
- Angiotensin II is a substance in the body which causes blood vessels to narrow, thus increasing blood pressure. Telmisartan works by blocking the effect of angiotensin II. When the effect of angiotensin II is blocked, your blood vessels relax and your blood pressure goes down.

- Amlodipine belongs to a group of medicines called calcium channel blockers. Amlodipine blocks calcium from moving into the cells of the heart and blood vessels. As a result, they relax the blood vessels and increase the supply of blood and oxygen to the heart while reducing its workload.

Both active ingredients work together to help stop your blood vessels tightening. As a result, the blood vessels relax and blood pressure is lowered.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You have or have had any of the following:**
 - biliary obstruction (problems with drainage of the bile from the liver and gall bladder)
 - severe liver problems
 - heart attack

- diabetes or kidney problems and you are taking aliskiren (a medicine used to treat high blood pressure).
- **You are pregnant.**
Telmisartan Amlodipine may affect your developing baby if you take it during pregnancy.
- **You are breastfeeding.**
Telmisartan Amlodipine may pass into human breast milk.
- **You are hypersensitive to Telmisartan Amlodipine, dihydropyridine derivatives or any of the ingredients listed at the end of this leaflet.**
Symptoms of an allergic reaction may include: cough, 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; fainting; or hay fever-like symptoms.
If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.
- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - liver problems
 - kidney problems or kidney transplant
 - heart problems

- recent severe diarrhoea or vomiting
 - a condition known as primary aldosteronism or hyperaldosteronism
 - diabetes
 - high levels of potassium in your blood
 - fructose intolerance or sorbitol intolerance.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant.
 4. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding
 5. You are planning to have surgery or an anaesthetic.
 6. You are currently receiving or are planning to receive dental treatment.
 7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Taking other medicines

Some medicines may interact with Telmisartan Amlodipine. These include:

- other medicines used to treat high blood pressure including ACE inhibitors, diuretic medicines (fluid pills), and aliskiren, especially if you have diabetes-related kidney problems.
- potassium supplements or potassium-containing salt substitutes
- lithium, a medicine used to treat mood swings and certain types of depression
- non-steroidal anti-inflammatory drugs (NSAIDs) or COX-2 inhibitors, medicines used to relieve pain, swelling and other symptoms of inflammation including arthritis
- anticonvulsant agents such as carbamazepine, phenobarbital,

- phenytoin, primidone (medicines used to treat epilepsy or fits)
- some antibiotics, such as 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.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with Telmisartan Amlodipine.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

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

How to take it

Swallow the tablet whole with a glass of water.

When to take it

Take this medicine at the same time each day. Taking it at the same time

each day will have the best effect and will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it for

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 missed dose 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 to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine

- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

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

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor

Things to be careful of

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

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

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking Telmisartan Amlodipine or if you have any questions or concerns.

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

Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- feeling light-headed, dizzy or faint
- 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
- headache
- taste disturbances or loss of taste
- shaking or tremors
- slow heart beat
- palpitations
- low blood pressure
- flushed or pale skin
- cough
- stomach pain
- diarrhoea
- feeling sick (nausea) or vomiting
- tender or enlarged gums
- an uncomfortable feeling in the stomach or belching after eating (indigestion)
- dry mouth
- 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

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

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

These are very serious side effects and you may need urgent medical attention or hospitalisation:

Allergic reactions

If you think you are having an allergic reaction to APO-Telmisartan Amlodipine, do not take any more of this medicine and

tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

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

Keep your medicine in a cool dry place where the temperature will stay 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Telmisartan Amlodipine Tablet looks like

- 40/5 mg Tablet: White and Blue coloured, two-layered, modified capsule-shaped, biconvex uncoated tablets with "APO" engraved on one side and "40/5" on the other side. White layer may contain blue specks and blue layer may contain white specks.
- 40/10 mg Tablet: White and Blue coloured, two-layered, modified capsule-shaped, biconvex uncoated tablets with "APO" engraved on one side and "40/10" on the other side. White layer may contain blue specks and blue layer may contain white specks.
- 80/5 mg Tablets: White and Blue coloured, two-layered, modified capsule-shaped, biconvex uncoated tablets with "APO" engraved on one side and "80/5" on the other side. White layer may contain blue specks and blue layer may contain white specks.
- 80/10 mg Tablets: White and Blue coloured, two-layered, modified capsule-shaped, biconvex uncoated tablets with "APO" engraved on one side and "80/10" on the other side. White layer may contain blue specks and blue layer may contain white specks.

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 inactive ingredients:

- Isomalt
- Mannitol
- Povidone
- meglumine
- sodium hydroxide

- calcium hydrogen phosphate anhydrous
- cellulose microcrystalline
- croscarmellose sodium
- silicon dioxide
- brilliant blue FCF Aluminium Lake
- iron oxide yellow
- iron oxide black.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Telmisartan Amlodipine 40/5 mg Tablet (Blister pack): AUST R 276429.

APO-Telmisartan Amlodipine 40/10 mg Tablet (Blister pack): AUST R 276427.

APO-Telmisartan Amlodipine 80/5 mg Tablet (Blister pack): AUST R 276426.

APO-Telmisartan Amlodipine 80/10 mg Tablet (Blister pack): AUST R 276424.

Sponsor

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