

Apo-Cilazapril/Hydrochlorothiazide

cilazapril 5mg + hydrochlorothiazide 12.5mg
film coated tablets

What is in this leaflet

Please read this leaflet carefully before you start using Apo-Cilazapril/Hydrochlorothiazide.

This leaflet answers some common questions about Apo-Cilazapril/Hydrochlorothiazide. 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 Apo-Cilazapril/Hydrochlorothiazide against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Apo-Cilazapril/Hydrochlorothiazide is used for

Apo-Cilazapril/Hydrochlorothiazide contains two active ingredients, cilazapril and hydrochlorothiazide.

Cilazapril belongs to a group of medicines known as ACE (Angiotensin Converting Enzyme) inhibitors. Hydrochlorothiazide belongs to a group of medicines known as thiazide diuretics.

Cilazapril and hydrochlorothiazide are both used to treat raised blood pressure. When used in combination they are more effective at lowering blood pressure than either medicine used alone.

Cilazapril works by inhibiting (blocking) natural chemicals produced by the body which increase blood pressure. This inhibition leads to a reduction of blood pressure. When given together with diuretics (fluid tablets) this helps to reduce the blood pressure further.

Your doctor may have prescribed Apo-Cilazapril/Hydrochlorothiazide for another reason.

Ask your doctor if you have any questions about why Apo-Cilazapril/Hydrochlorothiazide has been prescribed for you.

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

Before you use Apo-Cilazapril/Hydrochlorothiazide

When you must not use it

Do not use Apo-Cilazapril/Hydrochlorothiazide if:

- **You are allergic to cilazapril or other blood pressure medicines of the same class (called ACE inhibitors)**
- **You are allergic to hydrochlorothiazide, other thiazides or sulphonamide-derived medicines e.g. sulphamethoxazole (in co-trimoxazole, Deprim®, Trisul®) and sulphasalazine (Salazopyrin®)**
- **You have diabetes and/or kidney problems and you are taking a medicine which contains aliskiren**
- **You have previously suffered from angioedema (swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing), when taking other ACE inhibitors. Some people may be more likely to experience this than others.**
- **You are pregnant or breast feeding**
You should not take Apo-Cilazapril/Hydrochlorothiazide while pregnant. Your baby may absorb this medicine in the womb and therefore there is a possibility of harm to the baby.
- **You have no production or passing of urine (anuria)**
- **You are allergic to any of the ingredients listed at the end of this leaflet**
- **The package is torn or shows signs of tampering**
- **The expiry date printed on the pack has passed.**
If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure whether you should start using Apo-Cilazapril/Hydrochlorothiazide, talk to your doctor.

Before you start to use it

Tell your doctor if:

1. **You are currently on haemodialysis or haemofiltration (kidney replacement therapy)**
2. **You are breast feeding or plan to breast feed**
You should not take Apo-Cilazapril/Hydrochlorothiazide if you are breast feeding.

3. You have any other health problems, especially the following:

- liver disease
- kidney disease
- a heart condition
- blood disorders
- diabetes
- gout or history of gout
- you suffer from porphyria (a rare blood pigment disorder)

4. You are on a restricted salt diet

5. You are taking a medicine containing aliskiren, or are taking an Angiotensin II Receptor Blocker

6. You are taking potassium supplements or potassium-containing salt substitutes

7. You are allergic to any other medicines, foods, dyes or preservatives

8. You plan to have surgery (including dental surgery)

Tell your doctor if you are about to have any form of operation that requires an anaesthetic.

If you have not told your doctor about any of the above, tell them before you start using Apo-Cilazapril/Hydrochlorothiazide.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Apo-Cilazapril/Hydrochlorothiazide.

Some medicines may interfere with Apo-Cilazapril/Hydrochlorothiazide. These include:

- medicines used to lower blood pressure e.g. ACE inhibitors such as losartan (Cozaar®), candesartan (Atacand®); angiotensin receptor antagonists such as losartan (Cozaar®), candesartan (Atacand®); renin-inhibitors such as aliskiren (Rasilez); and diuretics including potassium sparing diuretics e.g. amiloride/hydrochlorothiazide (Moduretic®), amiloride/frusemide (Frumil®), spironolactone (Spiractin®, Spirotone®)
- other antihypertensive medicines e.g. amlodipine (Amlo®), clonidine (Catapres®), nifedipine (Adalat®)
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) used for the relief of pain e.g. aspirin, ibuprofen (Nurofen®), diclofenac (Voltaren®), naproxen (Naprosyn SR®)
- potassium supplements or potassium-containing salt substitutes used to reduce salt intake in the diet
- antipsychotic medicines used for the treatment of mania, hypomania and bipolar depression such as lithium (Lithicarb®, Priadel®)

- cardiac medicines used for the treatment of heart failure and certain types of arrhythmias e.g. digoxin (Lanoxin®)
- medicines used to treat irregular heart beat called class 1a or class III antiarrhythmics e.g. adenosine (Adenocor®, Leustatin®), lignocaine (Xylocaine®)
- medicines used to reduce cholesterol, treat pruritus and relief diarrhoea following surgery e.g. cholestyramine/colestipol (Questran®/Colestid®)
- medicines used to treat acute and chronic diarrhoea; ulcerative colitis; disease of the brain affecting movement; slow heart beat or to inhibit excessive saliva/mucous production pre surgery called anticholinergics e.g. atropine (Diastop®, Congentin®)
- medicines used in the management of cardiac arrest; asthma; emphysema; narcolepsy or allergic disorders called sympathomimetics e.g. adrenaline, salbutamol, ephedrine
- medicines used for the treatment of Parkinson's disease or infection caused by influenza e.g. amantadine (Symmetrel®)
- medicines used to lower blood sugar in diabetes (anti-diabetic medicines such as insulin or vildagliptin (Galvus®))
- medicines used to prevent organ transplant rejection or medicines used for some cancers e.g. sirolimus (Rapamune®) and everolimus (Afinitor®)
- desensitisation therapy with wasp or bee venom
- medicines which reduce the body's natural defences (immunosuppressive therapy) e.g. cyclosporine (Neoral®, Sandimmun®)
- medicine used to treat certain mental and emotional conditions; or medicine used to put you to sleep before surgery such as tricyclic antidepressants, antipsychotics, anaesthetics or narcotics
- medicines used for the treatment of Rheumatoid Arthritis e.g. gold
- medicines used to relax muscles called non-depolarizing muscle relaxants e.g. Atracurium, Mivacurium (Mivacron®)
- medicines used for the treatment of osteoporosis e.g. calcium salts and vitamin D
- medicines used for chemotherapy e.g. cytotoxic drugs such as methotrexate, cyclophosphamide,
- medicines used for the treatment of gout, or high uric acid levels in the blood which may cause gout e.g. allopurinol

These medicines may be affected by Apo-Cilazapril/Hydrochlorothiazide, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Apo-Cilazapril/Hydrochlorothiazide.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to use Apo-Cilazapril/Hydrochlorothiazide

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

How much to take

Take Apo-Cilazapril/Hydrochlorothiazide tablets exactly as your doctor has prescribed. The usual dose of Apo-Cilazapril/Hydrochlorothiazide is one tablet taken once daily.

How to take it

Swallow the tablet whole with a glass of water. Do not chew the tablets.

When to take it

Take Apo-Cilazapril/Hydrochlorothiazide tablets at about the same time every day.

It does not matter whether you take Apo-Cilazapril/Hydrochlorothiazide tablets with food or not. Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take the tablets.

How long to take it

Continue taking Apo-Cilazapril/Hydrochlorothiazide tablets until your doctor tells you to stop.

If you forget to take it

Do not take two doses on the same day.

If you remember your Apo-Cilazapril/Hydrochlorothiazide dose later on in the day you are meant to have taken it, then take the dose.

If you remember the next day, skip the missed dose and take your next dose when you are meant to.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering your dose, ask your pharmacist for some hints.

While you are using Apo-Cilazapril/Hydrochlorothiazide

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking Apo-Cilazapril/Hydrochlorothiazide.

Tell your doctor if you plan to have surgery (including dental surgery).

Tell your doctor if you become pregnant while taking Apo-Cilazapril/Hydrochlorothiazide.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Apo-Cilazapril/Hydrochlorothiazide.

Your doctor may monitor your blood while you are taking Apo-Cilazapril/Hydrochlorothiazide (for e.g. monitoring sugar levels, or liver and kidney function).

If you have any other laboratory tests, tell your doctor that you are taking Apo-Cilazapril/Hydrochlorothiazide.

There is an increased risk of non-melanoma skin cancer. You should regularly check your skin for new lesions and promptly report to your doctor any suspicious skin lesions so further investigations can occur.

Limit exposure to sunlight and UV rays and in the case of exposure to sunlight and UV rays use adequate sun-cream protection to minimise the risk of skin cancer.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel Apo-Cilazapril/Hydrochlorothiazide is not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Things you must not do

Do not stop taking Apo-Cilazapril/Hydrochlorothiazide tablets or change the dose without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not give Apo-Cilazapril/Hydrochlorothiazide to anyone else, even if they have the same condition as you.

Do not use Apo-Cilazapril/Hydrochlorothiazide to treat other complaints unless your doctor says to.

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how Apo-Cilazapril/Hydrochlorothiazide affects you. As with many other medicines used to treat high blood pressure, Apo-Cilazapril/Hydrochlorothiazide may cause dizziness, drowsiness or light-headedness in some people. Make sure you know how you react to Apo-Cilazapril/Hydrochlorothiazide before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy, drowsy or light-headed. If you drink alcohol, dizziness, drowsiness or light-headedness may be worse.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Apo-Cilazapril/Hydrochlorothiazide.

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

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Apo-Cilazapril/Hydrochlorothiazide.

Apo-Cilazapril/Hydrochlorothiazide helps most people with high blood pressure but it may have unwanted side effects in some 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 adverse effects.

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

Tell your doctor immediately or go to your nearest Accident and Emergency Centre if you notice any of the following:

- your face, lips, tongue and/or throat become swollen
- you develop a persistent pain in the abdomen
- symptoms of serious kidney failure, which may include passing little or no urine, drowsiness, nausea, vomiting and/or breathlessness
- chest pains, rapid or irregular heart beat
- difficulty breathing or coughing up blood
- symptoms of a stroke which may include weakness/numbness in the face, arms, legs or either side of your body, difficulty speaking, understanding or swallowing, loss of vision, severe and abrupt headache

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

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

- headache, dizziness, faintness
- tiredness
- cough, difficulty breathing, wheezing or breathlessness which may get worse when lying down
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- brain disease caused by liver illness (hepatic encephalopathy) - symptoms may include impaired consciousness, memory loss, personality changes, tremors, seizures, stupor or coma
- indigestion
- skin rashes or blisters
- bleeding or bruising more easily than usual
- nausea (feeling sick), vomiting, loss of appetite and/or taste, yellowing of the skin or eyes, light coloured bowel motions or dark coloured urine.
- feeling short of breath while exercising
- hair loss
- increased sensitivity to light
- constipation
- stomach pain
- muscle aches, tenderness, weakness or cramp
- swollen or painful joints
- dehydration, dry mouth or skin, excessive thirst or passing large amounts of urine
- eye problems
- trouble sleeping disruption in sleeping patterns
- depression
- sexual dysfunction
- new or suspicious skin lesions

These are the more common side effects of Apo-Cilazapril/Hydrochlorothiazide. Mostly these are mild and some may decrease as you get used to your medicine.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything on this list.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using Apo-Cilazapril/Hydrochlorothiazide

Storage

Keep your tablets in the pack or bottle until it is time to take them. If you take the tablets out of the pack or bottle they may not keep well.

Keep Apo-Cilazapril/Hydrochlorothiazide in a cool dry place where the temperature stays below 25°C. Protect from heat light and moisture.

Do not store it, or any other medicine in a bathroom or near a sink.

Do not leave it in the car or on window sills.
Heat and dampness can destroy some medicines.

Keep Apo-Cilazapril/Hydrochlorothiazide where young 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 Apo-Cilazapril/Hydrochlorothiazide, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

Apo-Cilazapril/Hydrochlorothiazide are pink, oval biconvex film-coated tablets. Each tablet is engraved "APO" on one side and "5" bisect "12.5" on the other side.

Available in HDPE bottles of 100 tablets.

Ingredients

Active ingredients:

- Each tablet of Apo-Cilazapril/Hydrochlorothiazide contains 5mg of cilazapril and 12.5mg of hydrochlorothiazide.

Inactive ingredients:

- Hyprollose (Hydroxypropyl cellulose)
- Hypromellose (Hydroxypropyl methyl cellulose)
- Iron oxide red (Red ferric oxide – orange shade #34690)
- Macrogol 8000 (Polyethylene glycol 8000)
- Titanium dioxide

- Maize starch (corn starch)
- Microcrystalline cellulose
- Sodium stearyl fumarate
- Purified water

This medicine is gluten and lactose free.

This medicine contains iron oxide red (orange shade# 34690)

Hydrochlorothiazide contains sulphur

Sponsor Details

Apo-Cilazapril/Hydrochlorothiazide is supplied in New Zealand by:

Apotex NZ Ltd
32 Hillside Road
Wairau Valley
AUCKLAND 0627

Telephone: (09) 444 2073

Fax: (09) 444 2951

Email: NZcustomerservice@apotex.com

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