APO-HYDROCHLOROTHIAZIDE TABLET

Hydrochlorothiazide (25mg,50mg)

What is in this leaflet

1. What Apo-Hydrochlorothiazide is used for
2. How Apo-Hydrochlorothiazide works
3. Before you use Apo-Hydrochlorothiazide
4. How to use Apo-Hydrochlorothiazide
5. While you are using it
6. Side effects
7. Storage and Disposal of Apo-Hydrochlorothiazide
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

What Apo-Hydrochlorothiazide is used for

Hydrochlorothiazide treats fluid retention (edema) in people with congestive heart failure, cirrhosis of the liver, or kidney disorders, or edema caused by taking steroids or estrogen.

This medication is also used to treat high blood pressure (hypertension).

How Apo-Hydrochlorothiazide works

Hydrochlorothiazide is a thiazide diuretic (water pill) that helps prevent your body from reabsorbing too much salt in the kidney, which can cause fluid retention.

Before you use Apo-Hydrochlorothiazide

- When you must not use it

Do not use this product if you:

- are allergic to hydrochlorothiazide, or any ingredients in this medication.
- are allergic to sulfonamide-derived drugs (sulfa drugs); most of them have a medicinal ingredient that ends in "-MIDE".
- have difficulty urinating or produce no urine.
- are breastfeeding. Hydrochlorothiazide passes into breast milk.
- have one of the following rare hereditary disease:
    - Galactose intolerance
    - Lapp lactase deficiency
    - Glucose-galactose malabsorption

Because lactose is a non-medicinal ingredient in Apo-Hydrochlorothiazide.

Pregnancy and lactation

Do not take Apo-Hydrochlorothiazide if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Apo-Hydrochlorothiazide if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Inform your healthcare providers before taking Apo-Hydrochlorothiazide if you:

- are allergic to penicillin
- have diabetes, liver or kidney disease.
- have lupus or gout.
- are dehydrated or suffer from excessive vomiting, diarrhea, or sweating.
- are less than 18 years old
- have had skin cancer or have a family history of skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Apo-Hydrochlorothiazide.
- have a greater chance of developing skin cancer because you have light-coloured skin, get sunburned easily, or are taking drugs to suppress your immune system.
- experience breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking Apo-Hydrochlorothiazide, seek medical attention immediately.

- Taking other medicines

As with most medicines, interactions with other drugs are possible. Tell your healthcare providers about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with Apo-Hydrochlorothiazide:

- Alcohol, barbiturates (sleeping pills), or narcotics (strong pain medications). They may cause low blood pressure and dizziness when you go from lying or sitting to standing up.
- Amphotericin B, an antifungal drug.
- Anticancer drugs, including cyclophosphamide and methotrexate.
- Antidepressants, in particular selective serotonin reuptake inhibitors (SSRIs), including citalopram, escitalopram, and sertraline.
- Antidiabetic drugs, including insulin and oral medicines.
- Bile acid resins used to lower cholesterol.
- Calcium or vitamin D supplements.
- Corticosteroids used to treat joint pain and swelling.
- Digoxin, a heart medication.
- Drugs that slow down or speed up your bowels, including atropine, metoclopramide, and domperidone.
- Drugs used to treat epilepsy, including carbamazepine and topiramate.
- Gout medications, including allopurinol and probenecid.
- Lithium used to treat bipolar disease.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen, naproxen, and celecoxib.
- Other blood pressure lowering drugs, including ACE inhibitor and Angiotension II receptor antagonist. When taken in combination with hydrochlorothiazide, they may cause excessively low blood

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pressure.
- Skeletal muscle relaxants used to relieve muscle spasms, including tubocurare.

Tell your doctor if you are using any other medications, including medications purchased without a prescription from a pharmacy, supermarket, or health food store.

How to use Apo-Hydrochlorothiazide

- How much to use

The usual maintenance adult dose for fluid retention treatment (diuresis) is 25-100mg per day depending on patient response. The usual adult dose for high blood pressure is 25-50mg once or twice daily.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Apo-Hydro for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think 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.

Taking too much of this medication might cause higher production of urine (diuresis), or dehydration.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

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

Tell your doctor immediately if you become pregnant while taking this medication.

Risk of skin cancer:
- Make sure to regularly check your skin for any new lesions. Check areas that are most exposed to the sun, such as the face, ears, hands, shoulders, upper chest and back.
- Limit your exposure to the sun and to indoor tanning. Always use sunscreen (SPF-30 or higher) and wear protective clothing when going outside.
- Talk to your doctor immediately if you get more sensitive to the sun or UV light or if you develop an unexpected skin lesion (such as a lump, bump, sore, or patch) during the treatment.

Hydrochlorothiazide in Apo-Hydrochlorothiazide can cause sudden eye disorders:
- Myopia: sudden nearsightedness or blurred vision.
- Glaucoma: an increased pressure in your eyes, eye pain. Untreated, it may lead to permanent vision loss.

These eye disorders are related and can develop within hours to weeks of starting Apo-Hydrochlorothiazide.

You may become sensitive to the sun while taking Apo-Hydrochlorothiazide. Exposure to sunlight should be minimized until you know how you respond.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Apo-Hydro to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Apo-Hydrochlorothiazide can cause side effects, although not everybody gets them.

Side effects may include:
- muscle cramps, spasms, and pain, weakness, restlessness
- dizziness, pins and needles in your fingers, headache
- constipation, diarrhea, nausea, vomiting, decreased appetite, upset stomach, enlargement of the glands in your mouth
- reduced libido
- bleeding under the skin, rash, red patches on the skin

If any of these affects you severely, tell your doctor, nurse or pharmacist.

Apo-Hydrochlorothiazide can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

Common:
- Low Blood Pressure: dizziness, fainting, lightheadedness. May occur when you go from lying or sitting to standing up.
- Decreased levels of potassium in the blood: irregular heartbeats, muscle weakness and generally feeling unwell

Uncommon:
- Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing
- Kidney Disorder: change in

APO-HYDROCHLOROTHIAZIDE TABLET

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frequency of urination, nausea, vomiting, swelling of extremities, fatigue
- Liver Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite
- Increased blood sugar: frequent urination, thirst, and hunger
- Electrolyte Imbalance: weakness, drowsiness, muscle pain or cramps, irregular heartbeat

Rare:
- Decreased Platelets: bruising, bleeding, fatigue and weakness
- Decreased White Blood Cells: infections, fatigue, fever, aches, pains, and flu-like symptoms

Very Rare:
- Toxic Epidermal Necrolysis: severe skin peeling, especially in mouth and eyes
- Acute respiratory distress (signs include severe shortness of breath, fever, weakness and confusion).

Unknown:
- Eye Disorders: Choroidal effusion: an abnormal building of liquid in your eye that may result in vision changes; Acute myopia: sudden near sightedness or blurred vision; Acute angle-closure glaucoma: a rapid increased pressure in your eyes, eye pain. If left untreated, it may lead to permanent vision loss.
- Anemia: fatigue, Loss of energy, weakness, shortness of breath.
- Inflammation of the Pancreas: abdominal pain that lasts and gets worse when you lie down, nausea, vomiting
- Skin and lip cancer (Non-melanoma skin cancer): lump or discoloured patch on the skin that stays after a few weeks and slowly changes. Cancerous lumps are red/pink and firm and sometimes turn into ulcers. Cancerous patches are usually flat and scaly.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Apo-Hydrochlorothiazide

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

- Disposal

Medicine should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Apo-Hydrochlorothiazide 25mg: Pale pink, round, flat-faced, bevelled-edged tablet. Scored & engraved APO over 25 on one side, other side plain.

Apo-Hydrochlorothiazide 50mg: Pale pink, round, flat-faced, bevelled-edge tablet. Scored & engraved APO over 50 on one side, other side plain.

- Ingredients
- Active ingredient: Hydrochlorothiazide
- Inactive ingredients Lactose monohydrate, microcrystalline cellulose, starch, magnesium stearate, colloidal silicon dioxide and sunset yellow aluminium lake 40%.

- MAL numbers:

Apo-Hydrochlorothiazide 25mg
MAL19984694ARZ

Apo-Hydrochlorothiazide 50mg
MAL19984688ARZ

Manufacturer

Apotex Inc.
50 Steinway Boulevard, Etobicoke,
Ontario, Canada, M9W 6Y3

Product Registration Holder

Pharmaforte (M) Sdn. Bhd.
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Date of revision

05 March 2026

Serial Number

NPRA(R2/2)260305/00025