

APO-ACETAZOLAMIDE TABLETS

Acetazolamide (250mg)

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What Apo-Acetazolamide is used for

Apo-Acetazolamide is used the following conditions:

- Lower pressure in the eye for people with glaucoma (a condition that damage the optic nerve and cause vision loss).
- Help control some types of seizures in people with epilepsy.
- Make urine less acidic to treat certain poisonings such as aspirin.

How Apo-Acetazolamide works

Apo-Acetazolamide is a medicine that works by blocking an enzyme called carbonic anhydrase. It reduces the fluid inside the eye which helps to lower pressure and it helps the body to get rid of extra salt, potassium and bicarbonate in urine to make the urine less acidic.

Before you use Apo-Acetazolamide

- When you must not use it

Do not take Apo-Acetazolamide if:

- you have low blood levels of sodium and potassium
- you have kidney problems, including kidney failure
- you have problems with your adrenal glands – glands above the kidneys
- you have a problem with your electrolytes causing an imbalance in your body's acid base balance (metabolic acidosis)
- you have severe liver problems
- you have severe glaucoma or hemorrhagic glaucoma

- you have a particular type of glaucoma known as chronic non congestive angle closure glaucoma
- you are pregnant

- Before you start to use it

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Apo-Acetazolamide. Talk about any health conditions or problems you may have, including if you:

- are breastfeeding. It is not known if acetazolamide passes into breastmilk.
- have experienced lung or breathing problems (such as fluid in the lungs) after taking acetazolamide in the past.

Other warnings you should know about:

Blood tests and monitoring: Acetazolamide can cause abnormal blood and urine test results. Your healthcare professional will decide when to perform the necessary tests and will interpret the results.

Eye problems: Acetazolamide can cause sudden eye disorders such as:

- Choroidal effusion: an abnormal buildup of liquid in your eye that may result in vision changes.
- Myopia: sudden nearsightedness or blurred vision.
- Glaucoma: an increased pressure in your eyes, eye pain. May lead to permanent vision loss if untreated.

If your vision changes, stop taking acetazolamide and seek medical help. These eye disorders are related and can develop within hours to weeks of starting acetazolamide.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

The effects of acetazolamide on pregnancy and the unborn child are not known. You should not take Apo-Acetazolamide if you are pregnant. Contact your doctor immediately if you become pregnant while taking Apo-Acetazolamide.

It is not known if acetazolamide passes into human breast milk. Ask your doctor or pharmacist for advice before taking Apo-Acetazolamide while breast-feeding.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription and herbal supplements.

Drugs that may interact with Apo-Acetazolamide include:

- Antacids
- Seizure medicines
- Sedatives
- Local anaesthetics
- Salicylates like aspirin

How to use Apo-Acetazolamide

Always take Apo-Acetazolamide exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- How much to use

- Chronic open angle glaucoma: 1 tablet 1 to 4 times a day.
- Secondary or acute glaucoma: 1 tablet every 4 hours.
- Epilepsy: Dose depends on weight.
- Alkalinizing Urine: 1 tablet every 4 to 6 hours.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Use this medicine for the duration that your doctor recommends.

- If you forget to take it

You should take it as soon as you remember. However, if this is within two hours of your next dose you should skip the missed tablet and carry on taking the rest of your tablets as usual.

- If you use too much (overdose)

Get medical help immediately, either by calling your doctor or going to the nearest hospital casualty department. Take any remaining tablets and this leaflet with you

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so that the medical staff know exactly what you have taken.

While you are using Apo-Acetazolamide

- Things you must do

Take your medicine exactly as your doctor has told you.

If you develop shortness of breath or difficulty breathing after taking Apo-Acetazolamide, seek medical attention immediately.

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

- 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 or pharmacist.

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

- Things to be careful of

Driving and using 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-Acetazolamide can cause side effects, although not everybody gets them.

Tell your doctor or pharmacist if you experience any of the following symptoms after taking this medicine.

Side effects may include:

- fever
- loss of appetite
- drowsiness
- confusion
- numbness or tingling of the skin
- muscle weakness

Apo-Acetazolamide may cause severe reactions. Stop using Apo-Acetazolamide and seek medical assistance immediately if you experience any of the following symptoms:

Common

- Bone marrow suppression: infections (fever, chills, sore throat, mouth ulcers), weakness, fatigue, easy bruising, bleeding of the nose, gums or mouth, tiny red spots on the skin, rash, shortness of breath, pale skin, lips and nail beds
- Kidney problems (including kidney stones): cloudy urine, blood in urine, urinating more than usual, sharp pain on the side and back, pain or burning when urinating, nausea, vomiting
- Serious skin reactions (Stevens Johnsons Syndrome, Erythema Multiforme, Toxic Epidermal Necrolysis and Acute Generalised Exanthematous Pustulosis): skin peeling, scaling, or blistering (with or without pus) which may also affect your eyes, mouth, nose or genitals, itching, severe rash, bumps under the skin, skin pain, skin color changes (redness, yellowing, purplish), swelling and redness of eyes or face, flu-like feeling, fever, chills, body aches, swollen glands, cough

Unknown:

- Abnormal bleeding: black tarry stool, blood in urine
- Eye problems:
 - Choroidal effusion: an abnormal building of liquid in your eye that may result in vision changes;
 - Acute myopia: sudden nearsightedness 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.
- Liver problems (including liver failure): yellowing of the whites of the eyes or skin, itchiness, dark urine, pale stool, weight gain, abdominal swelling and pain, loss of appetite, shortness of breath, disorientation or confusion.
- Lung problems (pulmonary edema (fluid in the lungs), acute respiratory distress syndrome, hypoxaemia (low oxygen in the blood): headache, coughing, wheezing, shortness of

breath, difficulty breathing, abnormal heart rate

- Seizures: fits, uncontrollable shaking of the body with or without loss of consciousness

Visit your doctor or pharmacist immediately if you experience any side effects after using 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-Acetazolamide

- Storage

Store below 30°C.

- Disposal

Medicines 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

White, round, biconvex tablet. Cross-scored on one side, other side engraved APO over 250.

- Ingredients

- Active ingredient(s)
Acetazolamide

- Inactive ingredients
Magnesium Stearate, Microcrystalline Cellulose, Colloidal Silicon Dioxide

- MAL number:

MAL19984701AZ

Manufacturer

Apotex Inc
150 Signet Drive, Toronto Ontario,
Canada M9L 1T9

Product Registration Holder

Pharmaforte (M) Sdn Bhd
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