SCHEDULING STATUS

S3

AZOMID 250 TABLET
Acetazolamide
Contains sugar (lactose monohydrate):
AZOMID 250: 150 mg per tablet

Read all of this leaflet carefully before you start taking AZOMID

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor,-pharmacist, nurse or other health care provider.
- AZOMID has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What AZOMID is and what it is used for

AZOMID is used for the treatment of acute primary and secondary glaucoma. AZOMID contains the active ingredient acetazolamide and belongs to a class of medicines known as carbonic anhydrase inhibitors. AZOMID works by reducing the rate at which fluid is produced in the eye, and thus decreases pressure within the eye.

2. What you need to know before you take AZOMID

Do not take AZOMID:

- if you are allergic to sulphonamides, sulphonamide derivatives including acetazolamide or to any of the ingredients in the medicine (listed in section 6).
- If you have low blood levels of sodium; sodium bicarbonate and/or potassium
- if you have reduced function of the adrenal glands – glands above the kidneys – (also known as Addison’s disease)
- if you have severe liver or kidney problems
- if you have a specific type of glaucoma known as chronic, non-congested closed angle glaucoma
- if you are in your first trimester of pregnancy

Warnings and precautions
Take special care with AZOMID:

- if you have a particular condition called hepatic cirrhosis (scarring and damage of the liver).
- if you are on long-term therapy with AZOMID, as you may experience low blood levels of sodium and potassium.
- if you are taking medication such as Quinidine, Methenamine or any psychostimulant drugs
- if you are being treated with anti-epileptics, as some patients have had thoughts of harming or killing themselves. If at any time you experience these feelings, immediately contact your doctor. Patients (and caregivers of patients) should to seek medical advice should signs of suicidal ideation or behaviour emerge.
- if you experience an unusual rash or a fever. If at any time you notice this, immediately contact your doctor.
- if you have pulmonary obstruction or emphysema (conditions that cause difficulty breathing and poor airflow to the lungs)
- if you have or ever had kidney problems such as kidney stones
- if you have intolerance to some sugars

AZOMID may affect some medical tests. If you visit a hospital or clinic for any medical tests, you should tell the doctor concerned that you are taking AZOMID. It is also advisable to do regular blood tests, as AZOMID may alter your blood cell counts.

Children and adolescents
Safety and efficacy in children have not been established.

Other medicines and AZOMID
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)
Tell your doctor or pharmacist if you are currently using:

- medicines that interfere with folic acid, e.g. methotrexate, pyrimethamine, or trimethoprim
- medicines used to decrease blood sugar levels (e.g. metformin, gliclazide)
- medicines used to prevent blood clots, such as Warfarin
- aspirin and related medicines, e.g. salicylic acid or choline salicylate used for mouth ulcers
- medicines for your heart such as cardiac glycosides (e.g. digoxin)
- medicines used to reduce blood pressure
- medicines used to treat epilepsy or fits (in particular, phenytoin, primidone or carbamazepine or topiramate)
- other medicines that are classified as carbonic anhydrase inhibitors (e.g. dorzolamide or brinzolamide, which are also used to treat glaucoma)
- amphetamines (a stimulant), quinidine (treats an irregular heartbeat), methenamine (prevents urine infections) or lithium (for the treatment of mental issues)

- ciclosporin (used to suppress the immune system)
- sodium bicarbonate therapy (used to treat high levels of acid in the body)
- medicines containing ammonium chloride

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Pregnancy
Taking AZOMID should be avoided in the first trimester of pregnancy.

Breastfeeding
Caution should be exercised if you are breastfeeding. Consult your doctor for advice.

Fertility
There is no information available on the effects of fertility.

Driving and using machines
If AZOMID makes you feel drowsy, dizzy, loss of balance or confused you should not drive or operate machines. AZOMID can occasionally cause short-sightedness; if this happens and you feel that you can no longer drive safely, you should stop driving and immediately contact your doctor.
It is not always possible to predict to what extent AZOMID may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measures to which AZOMID affects them.

AZOMID contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take AZOMID
Do not share medicines prescribed for you with any other person.
Always take AZOMID exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For the treatment of glaucoma:
The usual starting dose of AZOMID is 500 mg, which is equivalent to two tablets. Thereafter, you will take one 250 mg tablet every 6 to 8 hours.

Your doctor will tell you how long your treatment with AZOMID will last. Do not stop treatment early without consulting your health care provider first.
If you have the impression that the effect of AZOMID is too strong or too weak, tell your doctor or pharmacist.

If you take more AZOMID than you should
In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
Take the medicine pack with you. This is so the doctor knows what you have taken.

Treatment of overdose involves supportive measures to correct fluid and electrolyte balance. This will include either increasing or decreasing fluid intake and mineral supplementation if necessary.

If you forget to take AZOMID
Do not take a double dose to make up for the forgotten individual doses.

If you stop taking AZOMID
Talk to your doctor before you stop taking AZOMID.
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects
AZOMID can have side effects.

Not all side effects reported for AZOMID are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking AZOMID, please consult your health care provider for advice.

Tell your doctor immediately if you notice any of the following:
Side effects occurring frequently:

- Hyperpnoea (abnormally rapid or deep breathing)

Side effects occurring with unknown frequency:

- Agranulocytosis (low levels of granulocytes - a type of white blood cell)
- Aplastic anaemia (a condition that causes the bone marrow to stop producing new blood cells)
- Thrombocytosis (a condition in which your body produces too many platelets)
- Leukopenia (low levels of white blood cells)
- Bone marrow depression (a condition in which the bone marrow cannot make enough blood cells)
- Pancytopenia (low levels of all type of blood cells)
- Hypokalaemia acidosis (caused by low levels of potassium in the blood.)
- Thirst
- Metabolic acidosis (develops when too much acid is produced in the body usually due to kidney disease or failure)
- Electrolyte imbalance (when the body’s fluid or mineral levels are either too high or too low)

- Excitement
- Depression
- Irritability
- Reduced libido
- Occasional instances of confusion
- Drowsiness
- Numbness and tingling of face and extremities
- Dizziness
- Headache
- Ataxia (inability to coordinate muscle movements)
- Paraesthesia (sensations like numbness, tingling, pins and needles)
- Flaccid paralysis (weakness and looseness in the limbs)
- Transient myopia (near sightedness or short-sightedness)
- Tinnitus (ringing or buzzing in the ears)
- Hearing loss
- Gastrointestinal disturbances
- Melaena (abnormally dark tarry faeces, usually containing blood)
- Taste disturbances
- Nausea
- Vomiting
- Diarrhoea
- Fulminant hepatic necrosis (damage to liver cells causing liver injury)
- Hepatitis or cholestatic jaundice (build-up of bile leading to inflammation of the liver)
- Skin rash, including erythema multiforme (inflammation of the skin and skin lesions caused by an allergic reaction), Stevens-Johnson syndrome (life-threatening reaction with flu-like symptoms and painful rash affecting the skin, mouth, eyes and genitals), toxic epidermal necrolysis (skin disorder that causes blistering and peeling of skin)
- Urticaria (itchy rash)
- Thrombocytic purpura (rare disorder that causes blood clots to form in small blood vessels)
- Photosensitivity (sun-burn like reactions)
- Acute generalized exanthematous pustulosis – AGEP (a drug-related skin reaction)
- Renal lesions (Abnormal growths or masses on the kidney)
- Haematuria (blood in the urine)
- Crystalluria (particles in the urine)
- Renal and ureteral colic (urinary stones causing obstruction in urinary tract)
- Kidney failure
- Calculus formation (kidney stones)
- Glycosuria (sugar or glucose in the urine)
- Polyuria (increase in urine production)
- Fatigue
- Fever

- Anaphylaxis (sudden, severe allergic reaction with breathing difficulty, swelling, lightheadedness, fast heartbeat, sweating and loss of consciousness)
- Flushing (reddening of the skin)
- Abnormal liver function

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of AZOMID.

5. How to store AZOMID
- Store all medicines out of reach of children.
- Store in a cool dry place at or below 25 °C.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What AZOMID contains
The active substance is acetazolamide.
Each tablet contains 250 mg acetazolamide.
The other ingredients are maize Starch, pregelatinized starch, magnesium stearate and lactose monohydrate (sugar).
Preservative: Nipastat/Salistat (total parabens) 0,199 % m/m

What AZOMID looks like and contents of the pack
Tablets
White, round, normal biconvex tablet with quadrisected top, measuring 12,7 mm in diameter.

AZOMID tablets are packaged in white, polypropylene securitainer with LDPE (low density polyethylene) closure of 100 tablets.
White, cylindrical, screw type, HDPE (high density polyethylene) container with HDPE screw cap of 100 tablets.
Amber glass bottle with LDPE cap of 100 tablets.

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Customer Care: 0860 ADCOCK / (232625)

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