SCHEDULING STATUS

S3

ADCO-ALLOPURINOL 300 Tablets
Allopurinol

Contains sugar (lactose):
ADCO-ALLOPURINOL 300: 180 mg lactose per tablet

Read all of this leaflet carefully before you start taking ADCO-ALLOPURINOL

- 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.
- ADCO-ALLOPURINOL 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 ADCO-ALLOPURINOL is and what it is used for

ADCO-ALLOPURINOL is used for the treatment of gout and to prevent other conditions caused by hyperuricaemia (abnormally high levels of uric acid in the blood), such as kidney stones.
ADCO-ALLOPURINOL contains the active ingredient allopurinol and works by reducing the amount of uric acid in the blood.

2. What you need to know before you take ADCO-ALLOPURINOL

Do not take ADCO-ALLOPURINOL:

- If you are allergic to allopurinol or to any of the ingredients in ADCO-ALLOPURINOL (listed in section 6).
- If you are pregnant or breastfeeding
- If you have acute gout

ADCO-ALLOPURINOL is not recommended in children, except those with abnormal cell growth (malignancy)

Warnings and precautions

Take special care with ADCO-ALLOPURINOL:

- if you experience any skin rash or allergic reaction.ADCO-ALLOPURINOL treatment should be stopped and contact your doctor for advice.
- if you have an acute gout attack. ADCO-ALLOPURINOL treatment should not be started until the attack has subsided. Your doctor will advise on suitable treatment options to reduce inflammation during early stages of treatment.
- In children with Lesch-Nyhan syndrome. Increasing the daily fluid intake and taking urinary alkalinisers can minimize the formation of xanthine stones (kidney stones) in these children.
- if you suffer from or have a history of any urinary disorders, such as renal pelvic stones. Consult your doctor for advice.
- if you experience a fever or swelling under the skin
- if you have or ever had kidney or liver problems
- if you suffer from high blood pressure or a heart disorder and you are taking medicines to treat these conditions such diuretics or ACE inhibitors.
- if you experience a fever, weight loss or fatigue, as these are symptoms of vasculitis (inflammation of blood vessels).
- if you experience seizures, difficulty breathing, sweating, fast heartbeat or sweating.

Other medicines and ADCO-ALLOPURINOL

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 taking:

- Mercaptopurine, azathioprine or any other anti-neoplastic medicines (used to treat certain types of cancers).
- Chlorpropamide and some sulfonylurea antidiabetics (used in the management of high blood sugar).
- Vidarabine (used to treat viral infections such as herpes simplex).
- Medicines that can increase uric acid concentration, such as aspirin or other salicylates used for pain and inflammation.
- Probenecid (used to treat chronic gout)
- Anticoagulants such as Warfarin (used to prevent blood clots)
- Phenytoin (used to treat seizures and epilepsy)
- Theophylline (used in asthma and other respiratory disorders)
- Some antibacterial medicines such as amoxicillin or ampicillin (used to treat bacterial infections)
- Ciclosporin (used in organ transplants)
- Didanosine (used in the treatment of HIV/AIDS)

ADCO-ALLOPURINOL with food and drink

ADCO-ALLOPURINOL should be taken after meals with water to avoid nausea and vomiting.

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
You should not take ADCO-ALLOPURINOL if you are pregnant.

Breastfeeding
You should not take ADCO-ALLOPURINOL if you are pregnant.

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

Driving and using machines
ADCO-ALLOPURINOL can cause vision tiredness, light-headedness and dizziness in some people. If this happens to you, avoid activities which require you to be alert; for example, driving a car and using machinery.

It is not always possible to predict to what extent ADCO-ALLOPURINOL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities they are aware of the measure to which ADCO-ALLOPURINOL affects them.

ADCO-ALLOPURINOL 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 ADCO-ALLOPURINOL
Do not share medicines prescribed for you with any other person.
Always take ADCO-ALLOPURINOL exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Doses up to and including 300 mg of ADCO-ALLOPURINOL may be taken once a day. Your doctor will decide on the correct dose, depending on your body’s response and by monitoring your uric acid serum levels.
In severe conditions, doses of up to 600 mg may be required.

It is recommended that ADCO-ALLOPURINOL be taken after meals for better tolerance.

Children
The suggested initial dose is 8 mg/kg body mass daily.
You should take adequate amounts of fluid (at least 2 litres) during the day while on

treatment with ADCO-ALLOPURINOL.
The doses will be reduced for patients with kidney problems.

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

If you take more ADCO-ALLOPURINOL 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.

The most likely reaction would be gastro-intestinal intolerance.
Other symptoms of overdose include nausea, vomiting, diarrhoea and dizziness.

Treatment of overdose involves supportive measures such as administering sufficient fluids to facilitate excretion of ADCO-ALLOPURINOL from the body.
If necessary, haemodialysis may be used (a process whereby a machine filters and cleans the blood in the body)

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

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

4. Possible side effects
ADCO-ALLOPURINOL can have side effects.
Not all side effects reported for ADCO-ALLOPURINOL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ADCO-ALLOPURINOL, please consult your health care provider for advice.

Tell your doctor immediately if you notice any of the following:
Side effects occurring less frequently:
- Furunculosis (pus-filled bumps under the skin caused by infection of the hair follicles)
- Aplastic anaemia (a condition that causes the bone marrow to stop producing new blood cells)
- Thrombocytopenia (a condition in which your body has too less platelets)
- Leukopenia (low levels of white blood cells) or Leukocytosis and Eosinophilia (high) levels of white blood cells

- Bone marrow depression (a condition in which the bone marrow cannot make enough blood cells)
- Haemolytic anaemia (excessive breakdown of red blood cells)
- Agranulocytosis (very low level of a type of white blood cell, granulocytes)
- Skin rash 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), enlarged lymph nodes, flaky skin and angioimmunoblastic lymphadenopathy.
- Vasculitis (inflammation of blood vessels)
- Joint pain
- Drowsiness
- Diabetes
- High blood levels fat in the blood (Hyperlipidaemia)
- Depression
- Dizziness
- Headache
- Ataxia (inability to coordinate muscle movements)
- Paraesthesia (sensations like numbness, tingling, pins and needles)
- Seizures
- Coma
- Paralysis
- Weakness, numbness and pain in the hands and feet from nerve damage
- Cataract (clouding of the lens)
- Visual disturbances
- Macular changes (an eye disease that causes vision loss)
- Vertigo (a spinning sensation)
- Angina (pains to the chest, jaw and back, brought on by physical effort and due to problems with the blood flow to the heart)
- Bradycardia (slow heart rate)
- Hypertension (high blood pressure)
- Nausea
- Vomiting
- Abdominal pain
- Diarrhoea
- Gastric irritation
- Taste disturbances
- Recurrent haematemesis (vomiting blood)
- Steatorrhoea (oily, smelly stools, which often float)
- Stomatitis (inflammation of the lining of the mouth)
- Changed bowel habit
- Liver damage and impaired liver function
- Inflammation of the liver

- Hair loss
- Angioedema
- Discoloured hair
- Muscle aches
- Kidney damage
- Haematuria (blood in the urine)
- Uraemia (high levels of urea in the blood)
- Gynaecomastia (abnormal breast enlargement)
- Male infertility
- Erectile dysfunction
- Fever and chills
- Malaise (feeling generally unwell)
- Oedema (fluid retention)
- Asthenia (weakness)

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 ADCO-ALLOPURINOL.

5. How to store AZOMID

- Store all medicines out of reach of children.
- Store in a cool dry place at or below 30 °C.
- Protect from light and moisture
- 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 ADCO-ALLOPURINOL contains
The active substance is allopurinol.
Each tablet contains 300 mg allopurinol.

The other ingredients are lactose, magnesium stearate, maize starch, polysorbate 80, sodium starch glycollate, talc
croscarmelose sodium, lactose, maize starch, povidone K25.

What ADCO-ALLOPURINOL looks like and contents of the pack
Tablets
White, bisected, biconvex tablets.

ADCO-ALLOPURINOL 300:
30 and 250 tablets packed in white polypropylene securitainers with LDPE (low density polyethylene) closures.
30 and 250 tablets packed in white HDPE (high density polyethylene) containers with HDPE closures.
30 and 1000 tablets packed in clear PVC film/ printed aluminium foil blister packs in a cardboard carton.

Holder of Certificate of Registration
Adcock Ingram Limited
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Customer Care: 0860 ADCOCK / ~~(~~232625~~)~~

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