# **ZYLORIC TABLET**

Allopurinol (100mg, 300mg)

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### What Zyloric is used for

Zyloric is used to treat the following conditions:

- high levels of uric acid in the blood (hyperuricemia) associated with gout or when you are having treatment for cancer.
- Kidney stones formation or certain other types of kidney problems.

### How Zyloric works

Zyloric contains Allopurinol as the active ingredient. Allopurinol works by reducing the amount of uric acid in the body. Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have

prescribed it for another reason.

### Before you use Zyloric

- When you must not use it Do not take this medicine if you have an allergy to:
- Allopurinol
- any of the other ingredients listed at the end of this leaflet
- serum urate concentration is increased without deposition signs of uric acid

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

- <u>Before you start to use it</u>
  Tell your doctor if you have
  allergies to any other medicines,
  foods, preservatives or dyes.
  Tell your doctor if you have or
  have had any of the following
  conditions:
- Kidney disease
- · Liver disease
- Heart problems or high blood pressure and you are taking diuretics and/or a medicine called ACEinhibitors
- Serious skin rashes
   (Stevens-Johnson syndrome
   (SJS), toxic epidermal
   necrolysis (TEN),
   hypersensitivity syndrome
   called Drug Rash with
   Eosinophilia and Systemic
   Symptoms (DRESS)).
- · sugar intolerance
- · acute gout attack
- cancer
- certain enzyme disorders Tell your doctor if you are pregnant, plan to become pregnant or breastfeeding. Your doctor will discuss with you the risks and benefits involved. If you have not told your doctor any of the above, talk to he/she before taking Zyloric.
- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. Some medicines and Zyloric may interfere with each other. These include:

 medicine used for chemotherapy (e.g. 6mercaptopurine, azathioprine and Cyclophosphamide)

- vidarabine, used to treat chickenpox
- medicines used to reduce uric acid levels (e.g. Probenecid)
- aspirin
- medicine used to treat diabetes (e.g.
   Chlorpropamide)
- medicines used to thin the blood (Anticoagulants e.g. Warfarin)
- medicine used to treat fits (epilepsy) (e.g. Phenytoin)
- theophylline, used for breathing problems
- medicines used to treat bacterial infections (antibiotics e.g. Ampicillin and Amoxicillin)
- cyclosporine is a medicine used to suppress the immune system following organ transplant
- didanosine, used to treat HIV infection

These medicines may be affected by Zyloric or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

If you not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

### How to use Zyloric

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

- How much to use

The usual starting dose for adults is 100mg daily. The following dosage schedules are suggested:

- 100 to 200mg daily in mild conditions
- 300 to 600mg daily in moderately severe conditions
- 700 to 900mg daily in severe conditions

Children under 15 years 10 - 20 mg/kg body weight daily up to a maximum of 400mg daily.

Lower doses are used in the elderly or if you have kidney impairment, liver impairment.

- When to use it
  Take Zyloric after meal.
- <u>How long to use it</u> Continue taking Zyloric for as long as your doctor recommends.
- If you forget to use it

Take your dose as soon as you remember, and continue to take it as you would normally. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

# - <u>If you use too much</u> (overdose)

Immediately telephone your doctor for advice or go to Emergency Department at your nearest hospital if you think that you or anyone else may have taken too much Zyloric. Do this even if there are no signs of discomfort or poisoning syndrome including nausea, vomiting, diarrhoea and dizziness.

You may need urgent medical attention.

### While you are using it

- Things you must do
Tell all the doctors, dentists and pharmacists who are treating you that you are taking Zyloric.
Immediately stop taking
Zyloric and check with your doctor if a skin rash or other allergic reaction occurs.
If you are about to start taking any new medicine tell your doctor and pharmacist that you are taking Zyloric.

- Things you must not do
Do not stop taking your
medicine or lower the dosage
without checking with your
doctor.

Do not take Zyloric to treat any other complaints unless your doctor tells you to.
Do not give your medicine to anyone else, even if they have the same condition as you.

- <u>Things to be careful of</u> Zyloric may make some people feel drowsy, giddy or have problems with coordination, do not driving or operating machinery if you are affected.

### **Side effects**

effects:

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

The most common side effect is serious skin rash.

Stop taking allopurinol and contact your doctor immediately, if you experience the following side

- cancer in lymphatic system that cause fastgrowing of white blood cells
- allergic reaction: itchy or flaky skin rash, bruising or peeling off of the skin, fever, swollen lymph glands, joint pain, change in blood composition.
- Related to inflammation of blood vessel and tissue: enlargement of both liver and spleen, inflammation of the liver (hepatitis), kidney failure, seizure.

If you have kidney and/or liver problems, you may have an increased chance of getting side effects like:

- lowered white blood cell count
- blood deficiency and caused failure on bone marrow development
- low platelet count

The following side effects may occur with this medicine:

- boils, diabetes, high level of fat in the blood
- depression, coma, paralysis, nerve disorders including lack of muscle control, pin and needles, sleepiness, headache, change in taste
- cataract, visual impairment
- dizziness, chest pain, slow heart beat, high blood pressure
- vomiting, nausea, vomiting blood, offensive fatty diarrhoea, swollen mouth, change in bowel habits
- abnormal in liver function test
- swelling of the subdermal layers of skin
- hair loss, changes in hair colour
- blood in urine, high level of urea in blood
- infertility in male, difficulty maintain an erection, enlargement of breast in men
- water retention, feeling or being sick, tiredness.

Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking this medicine.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

# Storage and Disposal of Zyloric

- Storage

Keep your medicine in its original packaging until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

Store below 30°C.

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

Keep it where children cannot reach it.

### - <u>Disposal</u>

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

### **Product Description**

- What it looks like
Zyloric Tablet 100mg:
Round, white biconvex,
bisected tablets, debossed with
Z1 on one side.
Zyloric Tablet 300mg:
Round, white biconvex,
bisected tablets, debossed with
Z3 on one side.

# - <u>Ingredients</u>

Active ingredient:

- Allopurinol Inactive ingredients:
- Povidone
- Maize starch
- Lactose monohydrate
- Magnesium stearate

### - <u>MAL number</u> Zyloric Tablet 100mg:

MAL19973571AZ Zyloric Tablet 300mg: MAL19972499AZ

#### Manufacturer

Aspen Port Elizabeth (Pty) Ltd Corner of Fairclough and Gibaud Road Korsten 6020, Port Elizabeth, Republic of South Africa.

### **Product Registration Holder**

Aspen Medical Products Malaysia Sdn Bhd (1004761-W) Unit 1302A, Level 13A, Uptown 1, 1 Jalan SS21/58, Damansara Uptown, 47400 Petaling Jaya, Selangor, Malaysia.

### **Date of Revision**

28/07/2017

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