ZYLOPRIM

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ZYLOPRIM?

ZYLOPRIM contains the active ingredient allopurinol. ZYLOPRIM is used to treat: • gouty arthritis or gout • kidney stones • rare conditions where high levels of uric acid occur in the blood (for example, Lesch-Nyhan syndrome).

For more information, see Section 1. Why am I using ZYLOPRIM? in the full CMI.

2. What should I know before I use ZYLOPRIM?

Do not use if you have ever had an allergic reaction to ZYLOPRIM or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use ZYLOPRIM? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ZYLOPRIM and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use ZYLOPRIM?

- Swallow the tablets whole with a full glass of water.
- Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines
- People over 65 years of age, and those with kidney and/or liver problems should be started on the lowest dose possible to control uric acid production.

More instructions can be found in Section 4. How do I use ZYLOPRIM? in the full CMI.

5. What should I know while using ZYLOPRIM?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using ZYLOPRIM • Drink at least two litres (8 - 10 glasses) of fluid each day • Tell your doctor if you have an acute attack of gout while you are taking ZYLOPRIM • Tell your doctor immediately. If you become pregnant or plan to breastfeed while taking this medicine.
Things you should not do	• Do not use this medicine to treat any other complaints unless your doctor tells you to • Do not stop using this medicine or lower the dosage without checking with your doctor • Do not give this medicine to anyone else, even if they have the same condition as you.
Driving or using machines	• ZYLOPRIM may cause dizziness, drowsiness, lack of co-ordination in some people. Make sure you know how you are affected by this medicine before you drive or use machinery.
Drinking alcohol	• Tell your doctor if you drink alcohol.
Looking after your medicine	• Keep ZYLOPRIM in a cool dry place where the temperature will stay below 25°C.

For more information, see Section 5. What should I know while using ZYLOPRIM? in the full CMI.

6. Are there any side effects?

Serious side effects include: changes in vision, tingling or numbness of the hands or feet, a change in the amount of urine passed, yellowing of the skin and eyes (jaundice). Very serious side effects: asthma, wheezing or shortness of breath, swelling of the face, lips, tongue or throat which may cause difficulty in breathing, sudden or severe itching, skin, rash or hives.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

ZYLOPRIM

Active ingredient(s): *allopurinol*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZYLOPRIM. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ZYLOPRIM.**

Where to find information in this leaflet:

1. Why am I using ZYLOPRIM?
2. What should I know before I use ZYLOPRIM?
3. What if I am taking other medicines?
4. How do I use ZYLOPRIM?
5. What should I know while using ZYLOPRIM?
6. Are there any side effects?
7. Product details

1. Why am I using ZYLOPRIM?

ZYLOPRIM contains the active ingredient allopurinol.

ZYLOPRIM is used to treat:

• gouty arthritis or gout

• kidney stones

• rare conditions where high levels of uric acid occur in the blood (for example, Lesch-Nyhan syndrome).

It belongs to a group of medicines called anti-uricaemic agents.

This medicine works by reducing the production of uric acid in the body, therefore helping to prevent the formation of deposits of uric acid crystals. Deposits of uric acid crystals in the body can cause a variety of medical problems.

High levels of uric acid may cause gout attacks or kidney stones. Allopurinol is used to prevent gout attacks, not to treat them once they occur.

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.

This medicine is available only with a doctor's prescription.

Use in children

There is not enough information to recommend the use of this medicine for children.

2. What should I know before I use ZYLOPRIM?

Warnings

Do not use ZYLOPRIM if:

- You are allergic to allopurinol, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- You or a member of your immediate family has been diagnosed with haemochromatosis (a disease involving too much iron in the body) and you are taking iron salts.

Check with your doctor if you:

- had or have any other medical conditions including:
  - kidney problems, including kidney stones
  - liver problems
  - high blood pressure
  - heart problems
  - conditions where the levels of uric acid are abnormally high
  - cancer or tumours
  - thyroid problems.
  - diabetes
  - epilepsy

Tell your doctor if you are currently having an attack of gout.

Treatment with allopurinol should not be started until the attack has stopped, otherwise more attacks may occur.

(However, if an attack of gout occurs when a person is already taking allopurinol, it can be continued).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Allopurinol passes into breast milk and may affect your baby. Your doctor can discuss with you the risks and benefits involved.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ZYLOPRIM and affect how it works.

- angiotensin-converting Enzyme (ACE) inhibitors
- thiazide diuretics
- mercaptopurine, azathioprine or cyclosporin
- aspirin and other medicines known as salicylates
- probenicid
- warfarin and other coumarin type anticoagulant medicines
- chlorpropamide
- phenytoin
- certain antibiotics such as ampicillin and amoxycillin
- theophylline
- aluminium hydroxide
- adenine arabinoside ('Vidarabine'), an anti-viral medicine
- anti-cancer medicines (e.g. cyclophosphamide, doxorubicin, bleomycin, procarbazine and methochloroethamine)
- didanosine

Other medicines not listed above may also interact with allopurinol.

You should report any unexplained bruising or bleeding, sore throat, fever to your doctor immediately.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ZYLOPRIM.

4. How do I use ZYLOPRIM?

How much to take / use

- Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines
- Follow the instructions provided and use ZYLOPRIM until your doctor tells you to stop.

How to take ZYLOPRIM

Swallow the tablets whole with a full glass of water.

When to take / use ZYLOPRIM

- ZYLOPRIM should be used immediately after food, as this will lessen the chance of a stomach upset.
- Take your medicine at the same time each day. Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take it.
- ZYLOPRIM is usually taken once daily. However, if your dose is more than 300 mg, your doctor may advise you to take your medicine twice a day. Then, it should be taken morning and night, after breakfast and dinner.

How to long to take ZYLOPRIM

Continue taking ZYLOPRIM for as long as your doctor tells you.

ZYLOPRIM helps to control your condition, but does not cure it. It is important to keep taking ZYLOPRIM even if you feel well.

Make sure you have enough to last over weekends and holidays.

If you forget to use ZYLOPRIM

ZYLOPRIM should be used regularly at the same time each day.

If it is less than 4 hours to your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much ZYLOPRIM

If you think that you have used too much ZYLOPRIM, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include:

- nausea
- vomiting
- diarrhoea
- dizziness

5. What should I know while using ZYLOPRIM?

Things you should do

You should drink at least two litres (8 - 10 glasses) of fluid each day.

This will assist in reducing the uric acid levels in your body and prevent kidney stones from forming.

Tell your doctor if you have an acute attack of gout while you are taking ZYLOPRIM.

Your doctor may prescribe a medicine to relieve the acute attack. You can continue taking allopurinol.

If you are about to start any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Remind any doctor, dentist or pharmacist you visit that you are using ZYLOPRIM.
If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this ZYLOPRIM.

If you become pregnant or plan to breastfeed while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you should not do

- Do not take ZYLOPRIM to treat any other complaints unless your doctor tells you to.
- Do not give ZYLOPRIM to anyone else, even if they have the same condition as you
- Do not stop taking ZYLOPRIM or lower the dosage without checking with your doctor.
- Do not take ZYLOPRIM to treat an acute attack of gout.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ZYLOPRIM affects you.

ZYLOPRIM may cause (dizziness, drowsiness, lack of co-ordination etc.) in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your medicine in its original packaging until it is time to take it.
- Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal • stomach upsets, including ➢ nausea ➢ vomiting ➢ diarrhoea • change in bowel habits **Nervous System** • dizziness • drowsiness or unsteadiness when walking • headache • sleeplessness **Oral** • change in taste sensation **Skin and Subcutaneous Tissue** • hair loss or change in hair colour • skin rash **Urinary System** • a change in the amount of urine passed • going to the toilet more often **Metabolic and Endocrine** • feeling cold • weight gain • dry skin	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Nervous System • changes in vision • tingling or numbness of the hands or feet • dizziness • light-headedness • fainting, seizures or fits • nausea • vomiting • general feeling of illness or discomfort • fatigue • confusion • irritability **Urinary System** • a burning feeling while passing urine • blood in your urine **Hepatic (Liver) and Gastrointestinal** • yellowing of the skin and eyes (jaundice) • pain or fullness in upper abdomen • dark urine • pale, bulky, foul-smelling stool • vomiting blood **General Disorders** • generally feeling of being unwell or depressed • tiredness • flu like feeling • general body pain **Blood and Lymphatic System** • bleeding or bruising more easily • swollen lymph nodes • swollen glands in the neck, armpit, or groin **Cardiovascular System** • angina or palpitations • pain or tightness in the chest **Respiratory System** • asthma, wheezing or shortness of breath **Immune System / Hypersensitivity** • allergic reactions including swelling of face, lips, tongue or throat causing swallowing or breathing difficulty	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**
Skin and Subcutaneous Tissue • sudden or severe itching • severe skin rash or hives • redness, blistering and/or peeling of large areas of the skin **Musculoskeletal System** • joint pain or stiffness **Peripheral/Oedema** • swelling of the hands, ankles or legs, face **Signs of Frequent Infections** • high fever • severe chills • sore throat or mouth ulcers	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ZYLOPRIM contains

Active ingredient (main ingredient)	allopurinol
Other ingredients (inactive ingredients)	• lactose monohydrate • maize starch • povidone • sodium starch glycollate type A • sunset yellow FCF • stearic acid
Potential allergens	Contains sugars as lactose

Do not take this medicine if you are allergic to any of these ingredients.

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

What ZYLOPRIM looks like

ZYLOPRIM 100 mg tablets:

White, to off-white, colored round, biconvex uncoated tablets with 'AL' & '100' separated by breakline on one side and plain on the other side.

Bottle (HDPE white opaque bottle with screw cap) of 200's tablets. (Aust R 269649).

ZYLOPRIM 300 mg tablets:

Peach colored, round, biconvex uncoated tablets coded with 'AL' & '300' separated by breakline on one side and plain on other side.

Blister Pack (Clear PVDC/PVC/Aluminium silver foil) of 60's tablets. (Aust R 269645).

* Not all strengths, pack types and/or pack sizes may be available.

Who distributes ZYLOPRIM

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street

Cremorne, 3121 Australia

www.arrotex.com.au

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