

ZYLOPRIM™ Tablets

allopurinol

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about ZYLOPRIM (Allopurinol tablets).

It does not contain all of the available information about ZYLOPRIM tablets.

It does not replace talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you or your child taking ZYLOPRIM against the benefits he or she expects it will have.

Ask your doctor or pharmacist if you have any concerns about taking this medicine.

Keep this leaflet with the medicine.

You may need to read it again.

What is ZYLOPRIM

The name of your medicine is ZYLOPRIM and is available in tablets of two different strengths.

The active ingredient is called allopurinol.

Allopurinol belongs to a group of medicines called anti-uricaemic agents and is used to reduce the amount of uric acid in the body. Most commonly, high levels of uric acid in the body are related to gout.

ZYLOPRIM is available as a 100 mg and 300 mg tablet.

What ZYLOPRIM is used for

ZYLOPRIM is used to treat high levels of uric acid in the blood (hyperuricaemia) associated with gout or some other conditions. Your doctor will identify these other conditions if necessary, as they are very uncommon (e.g. Lesch-Nyhan Syndrome).

Your doctor however, may have prescribed ZYLOPRIM for another purpose not listed above.

Ask your doctor if you have any questions about why ZYLOPRIM has been prescribed for you.

If you have any concerns, you should discuss this with your doctor.

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

Before you take it

When you must not take it

Do not take ZYLOPRIM if you are allergic to:

- Allopurinol or any of the ingredients listed at the end of this leaflet including lactose.

Some of the symptoms of an allergic reaction to ZYLOPRIM may include urticaria and other skin rashes, difficulty breathing, hay fever, swelling of the face or throat or faintness.

Do not take ZYLOPRIM after the expiry date (EXP.) printed on the pack.

If you take it after the expiry date has passed, it may have no effect

at all, or worse, there may be an entirely unexpected effect.

Do not purchase or take ZYLOPRIM if the packaging is torn or shows signs of tampering.

Do not take the tablets if they do not look quite right.

If you are not sure whether you should start taking ZYLOPRIM, contact your doctor or pharmacist.

Do not give your medicine to children unless your doctor has prescribed it.

Before you start to take it

You must tell your doctor if you are:

1. **Allergic to any other medicines or any other foods, dyes or preservatives**

Some of the symptoms of an allergic reaction to ZYLOPRIM may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

2. **You have or have had any medical/ health problems, including:**

- kidney disease
- liver disease
- high blood pressure
- diabetes
- epilepsy
- heart disease
- haemochromatosis (a disease involving excessive deposits of iron in the body).

3. You are pregnant or plan to become pregnant

ZYLOPRIM like all medicines should not be used during pregnancy, unless your doctor tells you to.

4. You are breast-feeding or plan to breastfeed

5. Having an attack of gout

If a person first starts taking ZYLOPRIM when they are having an attack of gout it can make the symptoms of this condition temporarily worse. However, if an acute attack of gout does occur when a person is already taking ZYLOPRIM it can be continued. Do not stop taking this medicine during an attack of gout unless advised by your doctor.

If you have not told your doctor about any of the above, tell him or her before you start to take ZYLOPRIM.

Taking other medicines

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

SOME medicines may interfere with ZYLOPRIM.

These include:

- Aspirin (a drug which is used to treat headache, pain, inflammation, clotting or high temperatures). Other salicylate type drugs are also included. Ask your pharmacist.
- Coumarin type anticoagulant drugs, medicine used to prevent blood clots (e.g. warfarin)
- Other medicines used to treat gout or hyperuricaemia such as probenecid (Benemid)
- Some medicines used to suppress the immune system such as azathioprine (Imuran),

6- mercaptopurine and cyclosporin

- Some medicines used to treat epilepsy such as phenytoin (Dilantin)
- Theophylline (a drug used to treat asthma)
- Ampicillin or amoxycillin, which are two commonly used antibiotics used to treat bacterial infections
- Chlorpropamide (Diabinese) used to treat diabetes
- Medicines containing thiazide diuretics, used to decrease blood pressure and fluid retention (e.g. Chlorothiazide, hydrochlorothiazide, bendrofluzide)

The above medicines may reduce the effectiveness of ZYLOPRIM, reduce its own effectiveness and/or react with ZYLOPRIM resulting in untoward or sometimes dangerous side effects.

This list is not exhaustive. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking ZYLOPRIM.

How to take ZYLOPRIM

How much to take

The dose of ZYLOPRIM may be different for each person and their medical condition. Your doctor will decide the right dose for you.

The recommended doses are for:

- **Adults:** Usually 100 mg to 600 mg daily in divided doses (that is one 100 mg tablet daily up to one 300 mg tablet twice daily), but the dose may be as much as 900 mg daily to treat very high blood levels of uric acid.

- **Children under 15 years:** 100 mg to 400 mg daily in divided doses.
- Elderly patients usually receive the lowest dose possible to control uric acid production.

How to take ZYLOPRIM

Swallow the tablets with plenty of water and after food to reduce the possibility of gastric upset.

When to take it

Take ZYLOPRIM immediately after meals at the frequency directed by your doctor. For example, morning and night, after breakfast and dinner for a twice daily dosage.

If you forget to take it

If your dosing schedule is one dose a day, take the missed dose as soon as possible, but not later than 4 hours before your next dose.

If it is almost time for 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 it as you would normally.

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

Speak to your doctor or pharmacist if you are unsure about whether to take your next dose.

Do not try to make up for missed doses by taking more than one dose at a time. This may increase the chance of you getting an unwanted side effect.

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

If you take too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much ZYLOPRIM. Do this even if there are no signs of discomfort or poisoning. Also, report any other medicines or alcohol which has been taken. You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you take too much ZYLOPRIM you may have the following symptoms: nausea, vomiting and diarrhoea.

While you are taking ZYLOPRIM

Things you must do

Immediately stop taking ZYLOPRIM and check with your doctor if a skin rash or other allergic reaction occurs.

Take your medicine exactly as your doctor has prescribed. It is important to drink at least 2 litres of fluid per day. This will help prevent kidney stones.

ZYLOPRIM helps prevent, but does not relieve gout attacks. It is important that you continue taking ZYLOPRIM with the medication prescribed for gout attacks.

Tell all doctors, dentists and pharmacists who are treating you that you are taking this medicine.

Tell your doctor (immediately) if you become pregnant while you are taking it.

Visit your doctor regularly. Your doctor needs to check your

progress and see whether you need to keep taking ZYLOPRIM.

Always discuss with your doctor any problems or difficulties during or after taking ZYLOPRIM.

Tell your doctor if for any reason, you have not taken your medicine exactly as prescribed.

Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Keep enough ZYLOPRIM to last weekends and holidays.

Things you must not do

Do not take any other medicine while you are taking ZYLOPRIM without first telling your doctor.

Do not drive, operate machinery, or participate in any dangerous activities where alertness is required, until you know how ZYLOPRIM affects you.

ZYLOPRIM may cause dizziness and affect co-ordination in some people. Therefore, it may affect alertness or concentration. It can also affect your eyesight.

Make sure you know how you react to this medicine before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or have affected vision.

Do not take ZYLOPRIM for a longer time than your doctor has prescribed.

Do not change your dose without first checking with your doctor.

Do not stop taking it or lower the dose without checking first with your doctor.

Stopping this medicine suddenly on your own accord may cause some unwanted and dangerous effects, or your condition may reappear.

Your doctor will advise you when you can stop taking ZYLOPRIM completely.

Do not take this medicine to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ZYLOPRIM.

ZYLOPRIM helps most people with the medical conditions listed in the beginning of this leaflet, but it may have unwanted side effects in some people.

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist any questions you may have.

Common side effects:

The most common side effect is skin rash. Stop treatment with ZYLOPRIM immediately and contact your doctor if a rash does occur.

Tell your doctor if you notice any of the following:

- nausea (feeling sick)
- oedema (swelling)
- high blood pressure
- abdominal pain
- headache
- dizziness
- skin rash
- vomiting
- blurred vision
- unexplained nosebleeds

There are other side effects that occur less often.

If any of the following happen, stop taking ZYLOPRIM and tell your doctor immediately or go to

Accident and Emergency at your nearest hospital:

- fatty stools
- going to the toilet often
- blood in the urine
- hair loss
- general malaise or depression
- sleepiness
- confusion or vision problems
- numbness in the limbs
- angina (chest pain involving the heart)
- severe palpitations
- rash, itching or hives on the skin
- swelling of the face, lips, tongue or other parts of the body
- wheezing, shortness of breath, or trouble breathing
- pain or tightness in the chest
- if chills, fever, joint pain or swollen glands occur, especially if they occur together with or shortly after a skin rash

These are serious side effects. You may need urgent medical attention.

Serious side effects are rare.

Some people may get other side effects when taking ZYLOPRIM.

Your doctor may lower the dose to help control any serious side effects and decide on the necessary tests to monitor any of the above problems.

Check with your doctor as soon as possible if you have any problems while taking ZYLOPRIM, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

After taking ZYLOPRIM

Storage

Keep it where children cannot reach it.

A locked cupboard at least one and a half metres above the floor is a good place to store medicines.

Keep ZYLOPRIM in a cool dry place where the temperature stays below 30°C and protect from light. Do not store it or any other medicines in a bathroom or near a sink.

Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines.

Keep your tablets in the packs or bottles they were provided in until it is time to take them.

Disposal

If your doctor tells you to stop taking this medication OR it has passed the expiry date, ask your pharmacist what to do with any left over.

Product Description

What it looks like

ZYLOPRIM **100 mg** tablets are white, biconvex round tablets, one side embossed with 'AP' and '100' separated by a break line and plain on the other side; in bottles of 200.

ZYLOPRIM **300 mg** tablets are white, biconvex round tablets, one side embossed with 'AP' and '300' separated by a break line and plain on the other side; in blister packs of 60.

Ingredients

Each ZYLOPRIM 100 mg and 300 mg tablet contains the active ingredient allopurinol.

The non-active ingredients in each ZYLOPRIM tablet are:

- povidone
- maize starch
- lactose monohydrate
- stearic acid
- sodium starch glycollate (300mg strength only)

ZYLOPRIM tablets contain lactose but do not contain gluten or sucrose.

Sponsor or Supplier

Arrow Pharma Pty Ltd
15-17 Chapel Street
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The Australian Registration Numbers for
ZYLOPRIM 100 mg AUST R 286086
ZYLOPRIM 300 mg AUST R 286087

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