

Applicant/PHCR: Pharmacare Ltd
Product Proprietary name: ZYLOPRIM and ZYLOPRIM 300
Dosage form and strength: Tablet; 100 mg and 300mg
Each tablet contains allopurinol 100 mg
Each tablet contains allopurinol 300 mg

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1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

ZYLOPRIM* 100 mg tablets

Allopurinol

Contains sugar: Lactose monohydrate 50 mg

ZYLOPRIM* 300 300 mg tablets

Allopurinol

Contains sugar: Lactose monohydrate 150 mg

Read all of this leaflet carefully before you start using ZYLOPRIM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ZYLOPRIM 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 ZYLOPRIM is and what it is used for
2. What you need to know before you take ZYLOPRIM
3. How to take ZYLOPRIM
4. Possible side effects

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5. How to store ZYLOPRIM
6. Contents of the pack and other information

1. What ZYLOPRIM is and what it is used for

ZYLOPRIM contains the active substance allopurinol. ZYLOPRIM is used to prevent gout and other conditions associated with excess uric acid in the body . ZYLOPRIM should not be used to treat a sudden attack of gout.

2. What you need to know before you take ZYLOPRIM

Do not take ZYLOPRIM:

- If you are hypersensitive to allopurinol or to any of the other ingredients of ZYLOPRIM (listed in section 6).
- If you suffer from severe hepatic or renal disorder.
- If you suffer from an acute gout attack

Warnings and precautions

Take special care with ZYLOPRIM:

- If you suffer from severe kidney impairment. Your dose will need to be adjusted.
- If you have a history of liver disease or consume excessive quantities of alcohol.
- If you are of Han Chinese, African or Indian origin.
- If you have heart problems or high blood pressure and you are taking diuretics (water pill) and/or medicine called ACE inhibitors
- If you are currently having a gout attack.

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- If you have cancer or Lesch-Nyhan syndrome, the amount of uric acid may increase in your urine. To prevent this, you need to ensure to drink water sufficiently to dilute your urine.
- You may develop skin rashes when you take ZYLOPRIM. If you develop a rash or these skin symptoms, stop taking ZYLOPRIM and contact your doctor immediately.

Other medicines and ZYLOPRIM

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- Medicines used to treat mild to moderate pain to reduce fever or inflammation e.g. aspirin
- Medicine used for breathing problems e.g. theophylline
- Epilepsy medication e.g. phenytoin
- Medicine used to treat herpes or chickenpox e.g. vidarabine
- Medicine used to treat HIV infections e.g. didanosine
- Antibiotics e.g. ampicillin or amoxicillin
- Medicine for heart problems or high blood pressure ACE inhibitors or diuretics (water pills)
- Medicines for cancer treatment e.g. methotrexate
- Medicines used to reduce the immune response e.g. azathioprine
- Medication used to treat diabetes e.g. insulin
- Medicines used to thin your blood (anticoagulants) such as warfarin, heparin or

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rivaroxaban

- Any other medication to treat gout.

ZYLOPRIM with food and drink

It is recommended that ZYLOPRIM be taken after meals for reducing nausea and vomiting associated with the use of ZYLOPRIM.

Pregnancy and breastfeeding

The safety of ZYLOPRIM during pregnancy and whilst breastfeeding has not been established.

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

Driving and using machines

ZYLOPRIM is expected to influence your ability to drive. However, you should not drive, use machinery or perform any tasks that require concentration until you are certain that ZYLOPRIM does not adversely affect your ability to do so safely (see section 4)

ZYLOPRIM contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ZYLOPRIM.

3. How to take ZYLOPRIM

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

Adults: The usual starting dose is 100 mg daily, which may be taken as a single dose, after a meal. The tablets should be taken with a little water to make swallowing easier. The dose may be increased, usually to 300 mg daily, depending on the severity of your condition. Higher doses may be needed.

Elderly: Your doctor will prescribe the lowest dose of ZYLOPRIM that best controls your symptoms.

Children under 15 years: The usual dose is in the range of 100- to 400 mg daily.

If you have liver problems, your doctor will prescribe the lowest dose of ZYLOPRIM that best controls your symptoms.

If you have kidney problems, your doctor will prescribe the lowest dose of ZYLOPRIM that best controls your symptoms.

Do not stop taking your ZYLOPRIM tablets unless your doctor tells you to.

Your doctor will tell you how long your treatment with ZYLOPRIM will last. If you have the impression that the effect of ZYLOPRIM is too strong or too weak, tell your doctor or pharmacist.

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If you take more ZYLOPRIM than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take ZYLOPRIM

If you forget to take a dose, take another one as soon as you remember and then go on as before. Do not take a double dose to make up for forgotten individual doses.

If you stop taking ZYLOPRIM

Do not stop taking your ZYLOPRIM tablets unless your doctor tells you to.

4. Possible side effects

ZYLOPRIM can have side effects.

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

If any of the following happens, stop taking ZYLOPRIM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- A reaction of any kind such as a skin rash, flaking skin, boils or sore lips and mouth
- Blistering of the skin, mouth, eyes and genitals, sudden wheeziness, fluttering or tightness in the chest
- Toxic epidermal necrolysis (a rare, life-threatening skin condition that is usually caused

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by a reaction to the medicine. The top layer of skin detaches from the lower layers of the skin all over the body. TEN is a more severe form of Stevens–Johnson syndrome) These symptoms may mean that you are allergic to ZYLOPRIM.

These are all very serious side effects. If you have them, you may have had a serious reaction to ZYLOPRIM. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Angina, changes in the way your heart beats, for example, if you notice it beating faster
- Inflammation of the liver, which may show signs as follows: yellowing of the skin and eyes (jaundice), muscle aches, tiredness, itchy skin, nausea, vomiting, stomach pain, loss of appetite.
- Nausea and vomiting, vomiting of blood
- An increase in fat content in stools leading to the production of pale, bulky, offensive and loose stools, inflamed and sore mouth, change of bowel habit
- bleeding into the tissues, bruising, and slow blood clotting after injury.
- Fits, coma, paralysis, the loss of full control of bodily movements.

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

Less frequent side effects:

- Nausea (feeling sick) or vomiting
- Abnormal liver tests

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- Liver or kidney function may be affected
- infertility
- impotence
- enlargement of the breasts in men as well as women
- a change in your normal bowel habit
- change in taste perception
- hair loss or discolouration
- cataracts
- depression
- occasionally ZYLOPRIM tablets may affect your blood, which can manifest as bruising more easily than usual, or you may develop a sore throat or other signs of an infection. These effects usually occur in people with liver or kidney problems.
- high temperature
- blood in your urine (haematuria)
- high levels of cholesterol in your blood (hyperlipidaemia)
- a general feeling of being unwell or feeling weak
- weakness, numbness, unsteadiness on your feet or loss of consciousness
- headache, dizziness, drowsiness or disturbance of your vision
- lack of voluntary coordination of muscle movements (ataxia)
- sensation of tingling, tickling, pricking or burning of skin (paraesthesia)
- build-up of fluid leading to swelling (oedema) particularly of your ankles
- feeling thirsty, tired and losing weight; these may be symptoms of diabetes. Your doctor may wish to measure the level of sugar in your blood to help to decide if this is

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happening.

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, pharmacist or nurse. 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 ZYLOPRIM.

5. How to store ZYLOPRIM

Store all medicines out of reach of children.

Store at or below 25 °C in a dry place.

Protect from light.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ZYLOPRIM contains

ZYLOPRIM : The active substance is 100 mg allopurinol.

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The other ingredients are lactose monohydrate, maize starch, povidone and magnesium stearate.

ZYLOPRIM 300: The active substance is 300 mg allopurinol

The other ingredients are lactose monohydrate, magnesium stearate, maize starch, povidone.

What ZYLOPRIM looks like and contents of the pack

ZYLOPRIM :

Is a round, white biconvex, bisected tablet, debossed with Z1 on one side.

Clear plastic/silver aluminium blister packs of 30, 150, 300, packed in cartons.

ZYLOPRIM 300 :

Is a round, white biconvex, bisected tablet, debossed with Z3 on one side.

Clear plastic/silver aluminium blister packs 28, 30, packed in cartons.

Not all packs and packs sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

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Hotline: 0800 122 912

This leaflet was last revised in

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ZYLOPRIM: C974 (Act 101/1965)

ZYLOPRIM 300: G/3.3/51

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