

1.3.2 APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

PROPRIETARY NAME AND DOSAGE FORM:

ZYLOPRIM

Tablet

ZYLOPRIM 300

Tablet

Read all of this leaflet carefully before you start taking / using / are given ZYLOPRIM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- 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 ZYLOPRIM CONTAINS:

ZYLOPRIM

The active ingredient is allopurinol

Each tablet of ZYLOPRIM contains 100 mg of allopurinol.

The other ingredients are:

Lactose monohydrate, magnesium stearate, maize starch, povidone.

Contains sugar: Lactose monohydrate 50 mg

ZYLOPRIM 300

The active ingredient is allopurinol.

Each tablet of ZYLOPRIM 300 contains 300 mg of allopurinol.

The other ingredients are:

Lactose monohydrate, magnesium stearate, maize starch, povidone.

Contains sugar: Lactose monohydrate 150 mg

APPROVED INDICATION AND USE, THAT IS, WHAT THIS MEDICINE IS USED FOR:

ZYLOPRIM belongs to a group of medicines called enzyme inhibitors, which act to control the speed at which special chemical changes occur in the body. They are used to **prevent** gout and other conditions associated with excess uric acid in the body, including kidney stones and certain types of kidney disease. ZYLOPRIM should not be used to treat a sudden attack of gout.

INSTRUCTION BEFORE TAKING THE MEDICINE:

This medicine suits most people, but there are a few people who should not take it. Ask yourself these questions to see if ZYLOPRIM is right for you:

- Have you ever had an allergy (rash, itching, shortness of breath) to ZYLOPRIM, allopurinol or any of the other ingredients listed above?
- Are you having an attack of gout at the moment?
- Are you pregnant, trying to get pregnant, or breast-feeding?
- Are you suffering, or have you suffered from any liver or kidney disease?
- Are you taking medicines for heart disease or high blood pressure?

If you answer “**yes**” to any of the questions above, or if you are not sure, check with your doctor first before taking the medicine.

- ZYLOPRIM may cause drowsiness, giddiness and affect your co-ordination. If affected do not drive, operate machinery or participate in dangerous activities.

Warning:

ZYLOPRIM may interact with other medicines. It is important to let your doctor know if you are taking ANY other medication, especially if you are taking:

- Aspirin
- Theophylline
- Epilepsy medication
- Antibiotics
- Medicines for cancer treatment
- Medicines used to reduce the immune response
- Medication used to treat diabetes
- Medicines used to thin your blood (anticoagulants) such as warfarin
- Any other medication to treat gout

INSTRUCTIONS ON HOW TO TAKE THE MEDICINE:

You must take your ZYLOPRIM in the way your doctor has told you to. The amount of ZYLOPRIM that people can take can vary. The label on your pack will tell you how many tablets to take and how often to take them. If the label does not say or if you are not sure, ask your doctor or pharmacist.

Adults: The usual starting dose is in the range of 100-300 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 up to 900 mg daily, depending on the severity of your condition.

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 100-400 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.

If you forget to take a dose, take another one as soon as you remember and then go on as before.

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

SIDE EFFECTS:

Although rare, ZYLOPRIM may cause side effects in some people. If you experience any of the following while you are taking ZYLOPRIM, stop your tablets and tell your doctor as soon as possible:

- high temperature
- joint pain or painful swelling in the groin, armpits or neck
- jaundice (yellowing of the skin and eyes)
- nausea and vomiting (in some cases, blood may be present)
- a general feeling of being unwell
- weakness, numbness or loss of consciousness
- headache, dizziness, drowsiness or disturbance of vision
- chest pain, high blood pressure or a slow pulse
- retention of fluid leading to swelling (oedema) particularly of the 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 happening.

Check with your doctor **immediately** if you experience any of the following:

- a reaction of any kind such as a skin rash, flaking skin, boils or sore lips and mouth
- or very rarely, sudden wheeziness, fluttering or tightness in the chest; collapse

THESE SYMPTOMS MAY MEAN THAT YOU ARE ALLERGIC TO ZYLOPRIM. Do **NOT** take any more tablets unless your doctor tells you to do so.

Occasionally ZYLOPRIM tablets may affect your blood or lymphatic system. These effects have usually occurred in people with liver or kidney problems. However, tell your doctor as soon as you can if you notice that you are bruising more easily than usual, or if you develop a sore throat or other signs of an infection.

Rarely, ZYLOPRIM may affect your liver or kidney function. Very rare side effects of ZYLOPRIM include infertility, impotence, enlargement of the breasts, in men as well as women, a change in your normal bowel habit, change in taste perception, cataracts, hair loss or discolouration, convulsions, fits or depression.

Tell your doctor or pharmacist if you notice any other side effects, which are not mentioned here.

STORING AND DISPOSING OF ZYLOPRIM

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

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).

STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

PRESENTATION OF ZYLOPRIM

ZYLOPRIM: 30, 150 or 300 tablets are packed in a clear polyvinyl chloride or polyvinyl chloride/polyvinylidene chloride blister strip sealed with an aluminium foil backing. The blister strips are packed into an outer cardboard carton together with a leaflet.

ZYLOPRIM 300: 28 or 30 tablets are packed a clear polyvinyl chloride or polyvinyl chloride/polyvinylidene chloride blister strip sealed with an aluminium foil backing. The blister strips are packed into an outer cardboard carton together with a leaflet.

Not all packs and pack sizes are necessarily marketed.

IDENTIFICATION OF ZYLOPRIM:

ZYLOPRIM: A round, white biconvex, bisected tablet, debossed with Z1 on one side.

ZYLOPRIM 300: A round, white biconvex, bisected tablet, debossed with Z3 on one side.

REGISTRATION NUMBER:

ZYLOPRIM: C974 (Act 101/1965)

ZYLOPRIM 300: G/3.3/51

**NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE
CERTIFICATE OF REGISTRATION:**

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

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DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

Date of registration:

ZYLOPRIM: Old Medicine

ZYLOPRIM 300: 25 September 1974

Date of most recent amendment to the professional information as approved by the authority: 30 November 1993

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