

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**Purinol 100 mg and 300 mg Tablets**  
**Allopurinol**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What Purinol Tablets are and what they are used for
2. What you need to know before you take Purinol Tablets
3. How to take Purinol Tablets
4. Possible side effects
5. How to store Purinol Tablets
6. Contents of the pack and other information

**1. What Purinol Tablets are and what they are used for**

Purinol Tablets contain the active ingredient allopurinol, this belongs to a group of medicines called xanthine oxidase inhibitors, which act to control the speed at which certain chemical changes occur in the body.

Purinol tablets are used to treat conditions in which there is too much uric acid in the body such as:

- gout
- certain types of kidney disease and kidney stones
- cancer and some enzyme disorders which lead to the build up of uric acid (symptoms may include swelling and inflammation of the joints).

**2. What you need to know before you take Purinol Tablets**

**Do NOT take Purinol Tablets if you:**

- have had an allergic reaction to Purinol, allopurinol or any of the other ingredients (see section 6 and end of section 2)

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Purinol Tablets if:

- you are suffering, or suffered from liver or kidney disease
- you are taking medicines for heart disease or high blood pressure, e.g. diuretics (water tablets) or ACE inhibitors
- you are experiencing an acute attack of gout
- you are of Han Chinese, African or Indian origin
- you have thyroid problems.

**Take special care with Purinol Tablets:**

- if you have kidney stones. The kidney stones will become smaller and may have a small chance of entering and blocking your urinary tract.
- skin rashes have been reported in patients taking allopurinol. Frequently, the rash can involve ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These serious skin rashes are often preceded by influenza-like symptoms, fever, headache, body ache (flu-like symptoms). The rash may progress to widespread blistering and peeling of the skin. If you develop a rash or these skin symptoms, **stop taking allopurinol and contact your doctor immediately.**
- these serious skin reactions can be more common in people of Han Chinese, Thai or Korean origin. Chronic kidney disease may increase the risk in these patients additionally.
- if you have cancer or Lesch-Nyhan syndrome the amount of uric acid may increase in your urine. To prevent this, you need to assure to drink sufficiently to dilute your urine.

**Children**

Use in children is rarely indicated, except in some types of cancer (especially leukaemia) and certain enzyme disorders such as Lesch-Nyhan syndrome.

**Other medicines and Purinol Tablets**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription but particularly if you are taking:

- medicines used to reduce your immune response (immunosuppressants) e.g. 6-mercaptopurine, azathioprine and cyclosporin
- adenine arabinoside (vidarabine) (to treat herpes simplex infection or chickenpox)
- probenecid (for the treatment of gout)
- aspirin (or related drugs called salicylates, for pain relief)
- chlorpropamide (to treat diabetes; you may have low blood sugar)
- drugs used to thin the blood (anticoagulants) e.g. warfarin. You will need to be monitored carefully
- phenytoin (to treat fits, epilepsy)
- theophylline (to treat respiratory disease; you will be monitored carefully at the start of treatment or if your dose is increased)
- ampicillin or amoxicillin (antibiotics used to treat bacterial infections). You may develop a skin rash if taking these antibiotics with Purinol Tablets
- drugs used in the treatment of cancer
- didanosine (to treat HIV infection); this dose may be reduced while you are taking Purinol Tablets
- medicines for heart problems or high blood pressure such as ACE inhibitors or water tablets (diuretics)
- if aluminium hydroxide is taken concomitantly, allopurinol may have an attenuated effect. There should be an interval of at least 3 hours between taking both medicines
- with administration of allopurinol and cytostatics (e.g. cyclophosphamide, doxorubicin, bleomycin, procarbazine, alkyl halogenides), blood dyscrasias occur more frequently than when these active substances are administered alone. Blood count monitoring should therefore be performed at regular intervals.

**Taking Purinol Tablets with food and drink:**

The tablets should be taken with plenty of water after a meal. You should drink plenty of water during treatment with these tablets.

**Pregnancy and Breast-feeding:**

Tell your doctor if you are pregnant, think you may be pregnant or are planning to become pregnant, or if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine. Allopurinol is excreted in the human breast milk. Allopurinol during breastfeeding is not recommended.

**Driving and using machines:**

This medicine may cause drowsiness, or poor circulation. Do not drive or operate machinery until you know how these tablets affect you.

**Purinol 300 mg Tablets contain lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Purinol 300 mg Tablets.

**3. How to take Purinol Tablets**

Always take Purinol Tablets exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are uncertain. You should drink plenty of water during treatment with these tablets. You will be monitored regularly to check you are on the correct dose.

**Adults:**

The usual starting dose is 100 mg daily, which can be increased to 300 mg and may be taken as a single dose, after a meal. Take the tablets with plenty of water. The dose may be increased up to 900 mg daily, depending on the severity of your condition. Doses higher than 300 mg should be taken in divided doses not exceeding 300 mg at any one time.

**Older people:**

Your doctor may decide to use a lower dose than the above.

**Patients with kidney disease:**

Individuals with reduced kidney function may require fewer Purinol Tablets and the doctor will consider this when deciding the appropriate dose.

**For patients on dialysis:**

This drug is removed during dialysis and therefore an alternative dosing schedule will be considered by your doctor.

**Patients with liver disease:**

Reduced doses should be used in patients with liver disorders. Your doctor will advise you on the appropriate dose. Your liver function will be tested regularly.

**Children under 15 years:**

The usual dose is 100 mg to 400 mg daily and will depend on body weight.

**If you take more Purinol Tablets than you should:**

If you have taken more tablets than you should, contact your doctor immediately or go to your nearest hospital accident and emergency department. Take this leaflet and/or the pack with you. *Symptoms of an overdose* include feeling sick, being sick, diarrhoea and dizziness.

**If you forget to take your Purinol Tablets:**

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 a forgotten dose.

**If you stop taking the tablets**

Keep taking the tablets for as long as your doctor has told you to. Do not stop taking the tablets without asking your doctor first.

**If you have any further questions on the use of this product, ask your doctor or pharmacist.****4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Hypersensitivity**

**Uncommon** (may affect less than 1 in 100 people)

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

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

**Rare** (may affect less than 1 in 1000 people)

- Serious hypersensitivity reactions involving fever, joint pain, abnormalities in blood, bleeding in the lips, eyes, mouth, nose or genitals, ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes), widespread blisters or peeling

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

**Other side effects**

**Common** (may affect less than 1 in 10 people)

- skin rash
- increased level of thyroid stimulating hormone in the blood.

**Uncommon** (may affect less than 1 in 100 people)

- feeling sick (nausea) or being sick (vomiting)
- abnormal liver tests

**Rare** (may affect less than 1 in 1000 people)

- Liver problems such as liver inflammation

**Very rare** (may affect less than 1 in 10,000 people)

- 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, feeling unable to move muscles (paralysis) or loss of consciousness
- headache, dizziness, drowsiness or disturbance of vision
- chest pain (angina), high blood pressure or a slow pulse
- retention of fluid leading to swelling (oedema) particularly of the ankles
- abnormal glucose metabolism (diabetes). Your doctor may wish to measure the level of sugar in your blood to help to decide if this is happening
- occasionally Purinol tablets may affect your blood. 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. These effects usually occur in people with liver or kidney problems
- Purinol tablets may affect the lymph nodes
- male 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
- depression
- lack of voluntary coordination of muscle movements (ataxia)
- sensation of tingling, tickling, pricking or burning of skin (paraesthesia)
- occasionally Allopurinol 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. Tell your doctor as soon as possible.

If you experience any of these side effects, or if you notice any side effects not listed in this leaflet while you are taking Purinol tablets please tell your doctor or pharmacist at once.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL- Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: [www.hpra.ie](http://www.hpra.ie), e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Purinol Tablets**

- Keep out of the sight and reach of children
- Do not use these tablets after the expiry date shown on the label. The expiry date refers to the last day of that month
- Do not store above 25°C. Store your tablets in the original container.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. Contents of the pack and other information****Purinol Tablets contain:**

- The **active ingredient** is allopurinol. Each tablet contains either 100 mg or 300 mg of allopurinol
- The **other ingredients** are maize starch, powdered cellulose, colloidal anhydrous silica, magnesium stearate, sodium starch glycolate and povidone. In addition the 300 mg tablet contains lactose monohydrate (*see end of Section 2 for further information on lactose*) and sodium laurilsulfate.

**What Purinol Tablets look like and contents of the pack:**

Purinol 100 mg tablets are white, biconvex, engraved 1K1 with a breakline on reverse.

Purinol 300 mg tablets are white, biconvex, engraved 2K1 plain on reverse.

Purinol 100 mg Tablets are available in plastic containers, pack sizes of 100 and 500 tablets.

Purinol 300 mg Tablets are available in plastic containers, pack size of 100 tablets.

**Marketing Authorisation Holder and Manufacturer:**

Pinewood Laboratories Limited, Trading as Pinewood Healthcare, Ballymacarby, Clonmel, Co. Tipperary.

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PINEWOOD  
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